

PSJ14 Janssen Opp Exh 48 – MDL_RWJF_0000009

Additional award documents may be in materials in PIMS for this funding ID.

INDEX TO PRINCIPAL DOCUMENTS

The numbers assigned to each section refers to the tab under which the related documentation is filed. A mark in the box preceding any one section indicates that documentation appears in the folder on the subject outlined. Miscellaneous documentation is contained on the left side of the folder in reverse chronological order by date.

- ☒ 1. Grant Summary
- ☐ 2. Grant Results Report
- ☐ 3. Final Grantee Financial and Narrative Reports (letters of request, transmittal, and acknowledgement; follow-up correspondence)
- ☐ 4. Interim Grantee Financial and Narrative Report (letters of request, transmittal, and acknowledgement; follow-up correspondence; and grantee progress reports)
- ☒ 5. Grant Sign-off Sheet
- ☐ 6. Grant Award Letter (includes Grant Letter Information Sheet and Treasurer's Payment Letter)
- ☐ 7. Final Board Precis
- ☐ 8. New Releases and Related Press Coverage
- ☒ 9. Request for Project Support and General Conditions of Grant Form (includes Amendment Form(s); expenditure responsibility forms; and correspondence concerning change(s) in organization, project director, and/or address)
- ☒ 10. Tax Papers (all documentation and correspondence, including "reliance letter")
- ☐ 11. Proposal (proposal appendices and supplements, and CVs of project personnel)
- ☒ 12. Budget (final budget, revisions and correspondence)
- ☒ 13. Consultant reports, letters of project support, site visit reports

Grant Summary
ID# 043412

Awarded 04/29/02 - Active

University of Wisconsin-Madison Medical School (Madison,WI)

Program: (EOL) Targeted End-of-Life Projects Initiative
Project Title: National profile of pain relief and public policy
Project Director: David E. Joranson M.S.S.W. (608-263-7662)
Duration: 12 Months: 05/01/02 to 04/30/03
Team: HC/PMT - End of Life

Funding Class:	NP Implementation	Award Amount:	200,450
Renewal of:	036509	Actual Amount:	200,450
Funding Type:	N/A	Program Indicator:	In Program
Request Type:	Solicited	Precis Checked In:	No
Funding Category:	Targeted		

Goals: CHR(100%)
Interventions: Rsrch & Pol Anal(100%)

Board Date: 07/02	Board Class: B	Board Page:
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PO: Gibson, Rosemary
SO: Miller, Doriane C.
PA: Stives, Jeanne
FA: Kounelias, Sophia

Health Service Category

Continuum of Care:	End Of Life
	Treatment
Health Care Reform:	State
Pharmaceutical Services:	Pharmaceutical Services

Demographics

Age:	65 & over - Aging/Elderly/Senior Citizens
	N/A
Geographic Region:	N/A
Major City:	Unknown, N/A or N/S
Race/Ethnicity:	N/A
Segment:	N/A
Sex:	N/A
State:	Unknown, N/A or N/S
Urban/Rural Continuum:	Unknown, N/A or N/S

04/30/02 08 11 47 summary rw

MDL_RWJF_0000009

THE
ROBERT WOOD
JOHNSON
FOUNDATION®

1/3

December 5, 2003

Robert C. Andresen
Assistant Director of Post-Award Services
Research and Sponsored Programs
University of Wisconsin System
Bascom Hall, Room 201
750 University Avenue, Room 450
Madison, WI 53706-1490

Reference: I.D. #043412 - Final Financial Report Received/Closure of Grant

Dear Mr. Andresen:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative.

Your final financial report indicates that as of August 31, 2003, you have had cumulative expenditures of \$199,133. The Foundation has remitted payments to date totaling \$180,405 leaving you a cash deficit of \$18,728. Enclosed with this letter is our final payment in the amount of \$18,728.

This completes your financial reporting obligations with respect to this grant. We are glad we were able to assist you in this important endeavor.

Sincerely,



Sophia Kounelias
Grants Administrator

/SXX
Enclosure

cc: David E Joranson, M.S.S.W.
Rosemary Gibson



University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

November 7, 2003

Sophia Kounelias
Financial Analyst
The Robert Wood Johnson Foundation
Route 1 and College Road East
P. O. Box 2316
Princeton, N J 08543-2316

RECEIVED by:
NOV 12 2003

In reply, please refer to
UW Acct No. 133-EU26

RE: Grant # 043412

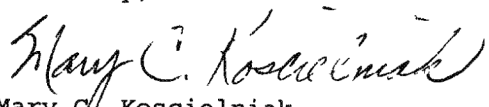
Dear Ms. Kounelias:

Enclosed is the final financial report on the above-referenced grant for the period May 1, 2002 through August 31, 2003 under the direction of David E. Joranson in the Pain & Policy Studies Group at the University of Wisconsin-Madison.

As the report indicates the total expenditures were \$199,133.24. Total payment to date from RWJ has been \$180,405.00. Would you please release the balance due of \$18,728.24.

Thank you for your support of this project. If you have any questions regarding this report, please contact me at 608/262-9028.

Sincerely,


Mary C. Koscielniak
Accountant

Enclosure

Cc: David Joranson - Pain & Policy Studies
Janet Kline - Pain & Policy Studies
Medical School Fiscal Services
File

FINANCIAL REPORT**The Robert Wood Johnson Foundation**

P.O. Box 2316

Princeton, NJ 08543-2316

Phone: (609) 452-8701 Fax: (609) 452-9564

UW Account #133-EU26

FA. SXX PA JMS PO. RG

Project Director David E. Joranson (608-263-7662)

Fiscal Officer Mark E. Inman (608-262-5415)

Grantee: University of Wisconsin-Madison

Grant Number: 043412

Budget Period: May-01-2002 to Aug-31-2003

Grant Period: May-01-2002 to Aug-31-2003

Budget for Year: 1

Revised: Jul-28-2003

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/02-10/02	Period 2 11/02-08/03	Total	Variance
PERSONNEL					
Project Director	34,640.00	13,738.40	20,901.84	34,640.24	(0.24)
Co-Director	16,274.00	6,393.12	9,881.24	16,274.36	(0.36)
Sr Policy Analyst	18,140.00	6,676.07	11,464.04	18,140.11	(0.11)
Policy Analyst	9,733.00	1,119.66	8,613.10	9,732.76	0.24
Communication Coord	11,608.00	4,601.68	7,006.20	11,607.88	0.12
Res Program Mgr	9,104.00	3,641.68	5,462.52	9,104.20	(0.20)
Program Assistant	5,590.00	2,129.44	3,460.34	5,589.78	0.22
Office Assistant	1,042.00	930.00	112.38	1,042.38	(0.38)
Fringe Benefits	34,846.00	12,721.65	22,124.02	34,845.67	0.33
Personnel Subtotal	140,977.00	51,951.70	89,025.68	140,977.38	(0.38)
OTHER DIRECT COSTS					
Supplies	2,412.00	1,410.63	1,288.30	2,698.93	(286.93)
Duplicating/Printing	12,505.00		13,712.44	13,712.44	(1,207.44)
Postage/Shipping	4,967.00	94.98	3,258.07	3,353.05	1,613.95
Teleconference	1,089.00		-	-	1,089.00
Computer System Support	10,000.00	-	10,000.00	10,000.00	-
Software	1,671.00	1,356.02	315.00	1,671.02	(0.02)
Travel	7,278.00	259.06	7,019.23	7,278.29	(0.29)
Other Direct Subtotal	39,922.00	3,120.69	35,593.04	38,713.73	1,208.27
CONSULTANT/CONTRACTUAL					
Cons/Contract Subtotal	3,000.00	-	3,000.00	3,000.00	-
INDIRECT COSTS					
	16,551.00	4,956.51	11,485.62	16,442.13 ✓	108.87
Grand Total	200,450.00	60,028.90	139,104.34	199,133.24	1,316.76


 Mark E. Inman, Administrative Officer

 SXX
 12/13/03

THE
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*See memo for
grant products*

October 10, 2003

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #043412 - Request for Final Financial Report

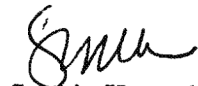
Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative.

We have received your final narrative report and have forwarded a copy of this report to Rosemary Gibson for her review. If she has any questions or comments, she will contact you directly.

We look forward to receiving your final financial report by October 23, 2003. If I can assist you further, please contact me at 609-627-5844.

Sincerely,



Sophia Kounelias
Financial Analyst

/SXX

cc: Robert C. Andresen
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

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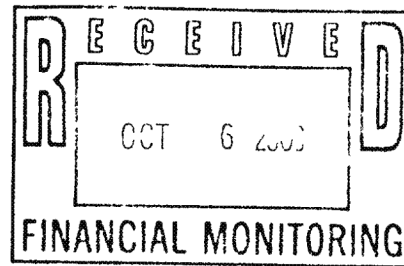
PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

October 2, 2003

Sophia Kounelias, Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Princeton, NJ 08543-2316



Reference: I.D. #043412

Dear Ms. Kounelias,

We are pleased to enclose the documentation required for completion of our grant, entitled "Pain Relief and Public Policy: Profile of a Nation." These documents include two copies each of the Final Report, the Bibliography, and the following grant products:

- A packet containing a cover letter, an FAQ, and a printed copy of "Achieving Balance in State Pain Policy: A Progress Report Card" (Progress Report Card)
 - The Progress Report Card contains a CD-ROM, which holds electronic versions of the Progress Report Card, the second edition of "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation," the cover letter, and the FAQ.

Sincerely,

A handwritten signature in cursive script, reading "Aaron M. Gilson".

Aaron M. Gilson, Ph.D.
Assistant Director

Enclosures

FINAL GRANT REPORT

**“PAIN RELIEF AND PUBLIC POLICY:
PROFILE OF A NATION”**

TARGETED END-OF-LIFE PROJECTS INITIATIVES

**GRANT # 043412
MAY 1, 2002-AUGUST 31, 2003**

**SUBMITTED
OCTOBER 2, 2003**

**PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU**

1. What measurable goals did you set for this project and what indicators did you use to measure your performance? To what extent has your project achieved these goals and levels of performance?

The purpose of this grant was to develop three products: (1) to prepare a Report Card on state pain policies as well as maps of pain policies and opioid consumption in the states; (2) to prepare an annual review of new state pain policies; and (3) to update the PPSG state pain policies database. Finally, we planned to: (1) upgrade and publicize the PPSG website, (2) increase awareness and use of PPSG products among key audiences, and (3) provide technical assistance and communicate our resources to the media, policymakers, regulators, and health-care professionals in pain management and end-of-life care.

Part 1: Elements of a National Profile

(1) Prepare a Report Card on State Pain Policies as Well as Maps of Pain Policies and Opioid Consumption in the States. This part of the project was refined considerably, leading to more timely, useful, and relevant products. We had proposed to use our existing 2000 policy database with some updates, but soon realized that the quality of the result would be greatly enhanced by a complete and systematic update of all state policies. We conducted a comprehensive update of policies as of March 2003, giving us a current database from which to calculate grades. This update also gave us the ability to compare 2003 policies with those from 2000, offering the opportunity to not only grade the states on the basis of recent data, but also to measure and report policy change that occurred during the three-year period. All policies were

evaluated using a methodology and criteria based on a Central Principle that has been described in the documents prepared according to this grant.

The resulting first-of-its-kind product was titled “Achieving Balance in State Pain Policy: A Progress Report Card” (*Progress Report Card*, or PRC), which not only grades states on the quality of their policies (i.e., statutes, regulations, and guidelines) that can enhance or impede pain management, but also provides a report of progress over the three-year period.

Further, PPSG staff decided to produce an updated “Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Second edition)” (*Evaluation Guide 2003*), which presents the evaluation of federal and state policies that was used to prepare the PRC. We felt that such a document would make it possible for users to know exactly how their state’s policies were evaluated. The *Evaluation Guide 2003* also contains a detailed discussion of the imperative to evaluate policy, the principle of balance, the evaluation criteria, the method used to evaluate state policies, and the complete text of the policy provisions that were identified in each state. This document is designed as a workbook to assist professionals and groups who want to learn how to evaluate policies that can affect pain management in their state or at the federal level; it also contains model language that can be used to improve state policies.

The PRC reports that, in 2003, the quality of state policies varied greatly, no state received an A or F, and a quarter of all states fall below the middle grade of C. A U.S. map of the states’ grades was included. We concluded that there is much room for progress. When examining the change that took place in state pain policy between 2000 and 2003, we found that 31% of states improved their policies sufficiently to increase their grade. Such improvement was largely driven by two factors: (1) healthcare regulatory boards adopting positive guidelines, and (2) legislatures repealing excessive restrictions that impede pain management. The forces that

helped to bring about these important changes in policy included the activities of state pain initiatives, community-state partnerships, units of the American Cancer Society, and key leaders in the fields of pain management and end of life care. In many cases, these groups used information and technical assistance that was available from the PPSG.

Indeed, these two reports, as well as the first edition of the *Evaluation Guide* that was published in 2000, were designed to be used as a tool for state agencies and professional organizations to evaluate and improve their state policies to promote adequate pain relief. Efforts are underway to develop a communications strategy to broadly disseminate and publicize the *Progress Report Card* and the *Evaluation Guide 2003*, hopefully leading to additional improvements in policy.

We had proposed to include data on states' consumption of opioid pain medications because these data had been difficult for others to obtain. However, after the grant was funded the U.S. Drug Enforcement Administration (DEA) made available these data on their website, at www.deadiversion.usdoj.gov/arcos/retail_drug_summary. The DEA's publication of these data made redundant their inclusion in the *Progress Report Card*.

The following professionals, who are health, legal, or communications experts and who are involved in policy issues affecting the treatment of cancer and non-cancer pain, served as advisors or reviewers for various aspects of this product: Matt Bromley, BS, Myra Christopher, BA, Carolen Collins, BA, June L. Dahl, PhD, William Marcus, JD, Ben Milder, BS, Rachel Reeder, MA, Carol Schadelbauer, BA, Jack Schwartz, JD, and Vicki Weisfeld, BA.

The *Progress Report Card* was printed as an attractive booklet and disseminated along with a CD that contained electronic versions of the *Progress Report Card*, the *Evaluation Guide 2003*, a cover letter, and an FAQ about policy and pain management issues. All documents also

were prepared in an electronic format and placed on the PPSG website. We automated the *Evaluation Guide 2003*'s state policy profiles; clicking the dot in a cell, which represents an identified policy provision, links the user directly to a down-loadable electronic document with the text of the provision that was identified, the citation, the applicable criteria, and a link to a more complete discussion of the criteria.

(2) Annual Review of New State Pain Policies. We had proposed to report on the dynamic nature of policy development in the states by producing an *Annual Review* of state pain policies that summarizes and comments on new or modified policies for the year 2002. However, we considered this to be redundant since our more comprehensive policy update identified these policy changes in the *Evaluation Guide 2003* and reported about them in the *Progress Report Card*.

(3) Update State Pain Policies Database. An essential component of the previously described work includes the maintenance and update of the PPSG federal and state pain policy database. To identify the policies for updating the database, we:

- Continued to use an electronic legal database called Lexis to search for and download policies;
- Periodically contacted all state medical, pharmacy, and nursing boards to obtain new policies that would not ordinarily be available from LEXIS, such as some administrative codes, guidelines, and policy statements;
- Contacted key informants who monitor the development of state pain policies to supplement data collection;
- Reviewed websites of regulatory boards or contacted boards to request policies directly; and
- Reviewed (1) all medical and pharmacy board newsletters that are available on the internet; (2) updates from the National Association of State Controlled Substances

Authorities; (3) newsletters such as the National Conference of State Legislatures' "State Health Notes;" (4) various email list serves; and (5) personal contacts.

This systematic data-collection process is considered essential to ensure that there is a reliable source of policy data that is available to be evaluated for the preceding projects. In addition, new policies are routinely proofed and added to the full-text policy database on the PPSG website to provide public access to pain policy.

Part 2: Communications and Technical Assistance

(1) Upgrade and Publicize PPSG website. The PPSG website continues to be a valuable resource to our communications program, allowing us to provide information, education, and policy research information to a broad national and international audience. We regularly receive positive feedback; the hit-rate is more than 350 users per day. We have added all new PPSG products to the website, including those produced for this grant; each time we add a significant product we communicate it to a large email list of users. We publicize the website frequently in publications of other groups and in presentations to key professional organizations. In addition, we have begun a project to re-design the website to further improve its appearance and organization, while maintaining its clarity, simplicity, efficiency, and reliability.

(2) Increase Awareness and Use of PPSG Products Among Key Audiences. We continued and expanded our efforts to disseminate PPSG policy products to key audiences. We expanded our email list using audience lists that we have developed through presentations at state and national conferences. We offer the opportunity for recipients to remove themselves,

but this seldom occurs. More often we receive requests to be added.

The information from our projects was published in relevant newsletters and journals read by key enforcement and regulatory audiences, as well as presented in national conferences. In addition, we maintained communication with organizations that are directly involved in efforts to improve end-of-life care, such as Last Acts, Community-State Partnerships, Cancer Pain Initiatives, American Cancer Society to alert them to the release of upcoming publications and products. As a result, a number of groups have published articles about our work, including the Last Acts publications *State Initiatives in End-of-Life Care* and *Innovations in End-of-Life Care*, the Federation of State Medical Board's *Federation Bulletin: Journal of Medical Licensure & Discipline*, and the Open Society Institute's *Ideas for an Open Society*.

Communicating the Progress Report Card. Although the communications plan for the *Progress Report Card* occurred after the grant period, we will briefly describe the dissemination strategy we developed. This involved sending an advance hard copy of the *Progress Report Card*, with attached CD, to several hundred organizations, including state medical and pharmacy boards, state attorneys general, community-state partnerships, state cancer pain initiatives, and legislative law librarians. The advance copy contained an embargo notice to prevent re-distribution prior to the release date. A national press release was issued in September, along with 14 releases tailored to those states that earned better grades. We collaborated with the University's Public Affairs Manager to publicize the *Progress Report Card* to a nationwide audience. Finally, with assistance from Last Acts, we presented to two national call-ins to provide information about the *Progress Report Card* and to answer questions to healthcare professionals. Because these events occurred after the grant ended, a more detailed description of dissemination activities and media coverage for these documents is available upon request.

(3) Technical Assistance. We proposed to develop communications strategies aimed at increasing awareness and use of these products by the media, policymakers, regulators, and healthcare professionals. We have provided technical assistance to members of the following organizations and state-level practitioners:

- American Alliance of Cancer Pain Initiatives
- American Cancer Society – National office
- American Cancer Society – New England division
- American Medical Association – Drug Policy Section
- California Department of Justice
- Connecticut Pain Initiative
- East Virginia Medical School
- Federation of State Medical Boards, Inc.
- Harvard Medical School
- Massachusetts Medical Board
- Massachusetts Pain Initiative
- Midwest Bioethics
- National Hospice and Palliative Care Organization
- New Jersey Department of Health and Senior Services
- Open Society Institute/Project on Death in America
- Oregon Health Sciences University
- Peter MacCallum Cancer Institute
- University of California-Davis
- University of Florida
- University of Wisconsin Medical School
- Wayne State University
- White House Office on National AIDS Policy
- Healthcare professionals in Massachusetts, Oklahoma, and Oregon

In addition to the presentations listed in the Bibliography, the PPSG provided assistance throughout the grant period to Last Acts.

PPSG participation in the Last Acts program. During the grant period, the PPSG cooperated extensively with Last Acts programs. The objective was to further education and

policy change to improve the regulatory environment for pain management and end-of-life care.

The Pain Forum was established in March, 2001, by Last Acts and the PPSG, and in cooperation with the American Pain Society and the American Academy of Pain Medicine, following an inquiry to the PPSG from the U.S. Drug Enforcement Administration about the possibility of producing a consensus statement about the need for a balanced response to abuse and diversion of opioid pain medications. Several meetings were held with a group of representatives of national pain and healthcare organization, co-chaired by Karen Kaplan and David Joranson. A consensus statement was drafted with assistance from the PPSG. Titled "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," it has been endorsed by a total of 42 organizations and the DEA, as well as the National Association of Attorneys General (NAAG). The value of the statement is that it clearly recognizes the principal of balance that the PPSG has developed, so that efforts to address diversion do not interfere in pain management

(<http://www.medsch.wisc.edu/painpolicy/Consensus2.pdf>). The second project of the Pain Forum, currently in process, is to develop an FAQ for physicians and drug investigators that addresses key questions relating to prescribing controlled substances for pain. DEA has offered to send the FAQ to all physicians who apply for new or renewed controlled substances registrations.

Last Acts established collaboration with the NAAG in an effort to draw the attention of the states' top law enforcement officers and legal counsels to the need for better end-of-life care as a consumer issue. The PPSG was invited to participate in several ways, including to present at their regional meetings about the regulatory barriers to pain management, and to assist with the drafting of a law review article to be authored by Drew Edmundson, president of NAAG.

The Director of the PPSG was appointed to the national advisory committee for the Robert Wood Johnson Foundation's Community-State Partnership initiative and grants program that was administered by the Midwest Bioethics Center; PPSG assisted with review of grant applications and site visits.

PPSG provided technical support to the RWJF Rallying Points program, through presentations at their regional meetings about improving the regulatory environment for pain management in end of life care.

In preparation of its Report Card "Means to a Better End," Last Acts used PPSG policy evaluations as part of its secondary data analysis for one section of its report, and members of the PPSG were involved in the press conference to publicize release of the Report Card.

PPSG was invited to write a special article for the Last Acts communications program *Innovations in End of Life Care*. The article, titled "Improving Availability of Opioid Pain Medications: Testing the Principle of Balance in Latin America" was featured on-line, and will be published in *Palliative Medicine*.

The PPSG research and education program was also featured in the Last Acts publication *State Initiatives in End of Life Care*.

2. DID THE PROJECT ENCOUNTER INTERNAL OR EXTERNAL CHALLENGES? HOW WERE THEY ADDRESSED? WAS THERE SOMETHING RWJF COULD HAVE DONE TO ASSIST YOU?

A challenge to creating the *Progress Report Card* was developing a methodology to grade and rank states based on the extent that their policies either enhance or impede pain management. We attempted to develop a system where negative criteria would be weighted

differently than positive criteria, and some criteria would be weighted more than others, depending on the level of evidence available to support their impact on pain relief. External reviewers, including Foundation grantees and Last Acts partners, provided critical feedback about this procedure and encouraged us to adopt a simpler grading methodology that was easier to justify. Our final grading system, which we believe is valid, involves calculating means and standard deviations using the cumulative distribution of equally-weighted positive and negative provisions from all states.

Another challenge followed from our decision that we needed to update the entire policy database and to produce the *Evaluation Guide 2003*. This effort, which we considered essential, required an additional use of resources that had not been anticipated.

3. HAVE THERE BEEN OTHER SOURCES OF SUPPORT?

This project had no other sources of support. The other activities of the group were international projects related to our designation as the World Health Organization Collaborating Center for Policy and Communications in Cancer Care. Office space for the PPSG and this project was provided by the Medical School of the University of Wisconsin-Madison.

4. WHAT LESSONS DID YOU LEARN FROM UNDERTAKING THIS PROJECT?

This project emphasized several important lessons that can perhaps be useful to others. This project reinforced the value of knowing the “critical path” (i.e., identifying those tasks that are likely to be complex and time-consuming). Focusing the necessary time and energy on those

tasks early significantly reduced the chance that their completion would cause major delays.

The project also reinforced the value of peer review (i.e., requesting a “critical read” and obtaining comments from knowledgeable colleagues). We found this to be very useful in evaluating specific issues that we knew would be difficult, contributing to a much better product. Additionally, one can get valuable feedback on new issues, as well as a sense for how a particular product may be received by and meet the needs of others in the field.

We also learned that, despite clear methods and great care, it is possible to overlook important policy information. Openness to feedback from others, and flexibility in responding to questions or concerns, is extremely important in order to accommodate corrections that are necessary.

5. WHAT IMPACT DO YOU THINK THE PROJECT HAS HAD TO DATE? WHO CAN BE CONTACTED A FEW YEARS FROM NOW TO FOLLOW UP ON THE PROJECT?

The grant has ended with the completion of the proposed products. We are now engaging in a large communications effort to publicize the results of the completed project, after which it will be possible to gauge impact. However, it is clear in the *Progress Report Card* that RWJF support for PPSG policy studies has resulted in measurable improvements in policy in the U.S.

6. WHAT ARE THE POST-GRANT PLANS FOR THE PROJECT IF IT DOES NOT CONCLUDE WITH THE GRANT?

All proposed products were completed within the timeframe of the grant. Additional

resources are necessary, however, to communicate the results of the *Progress Report Card* and the *Evaluation Guide 2003* so that they can be used as tools for policy change; we are currently searching for interested organizations to support our communications and technical assistance activities. We appreciate the assistance that has been provided by our Project Officer in this search.

7. WITH A PERSPECTIVE ON THE ENTIRE PROJECT, WHAT HAVE BEEN ITS KEY PUBLICATIONS AND NATIONAL/REGIONAL COMMUNICATIONS ACTIVITIES? DID THE PROJECT MEET ITS COMMUNICATIONS GOALS?

The purpose of this grant is continued support of the development of a national profile of pain relief and public policy. We believe we have achieved that purpose by developing products in addition to the *Progress Report Card* and communicating them to the large and expanding audience of those interested in pain management and end-of-life care.

Two articles published during this grant period helped us accomplish our communications goals. The first, titled “North Carolina, Pain Management and End-of-Life Care: Communicating the Policy,” describes the efforts of the North Carolina Medical Board (NCMB) to develop and communicate new pain-related policies to licensees and the public. The NCMB is an example of how a state medical board can be proactive in the development and implementation of policies to improve pain management and end-of-life care.

The second, “U.S. Policies Relevant to the Prescribing of Opioid Analgesics for the Treatment of Pain in Patients with Addictive Disease,” published in the *Clinical Journal of Pain*, discussed the status of federal and state policies governing the medical use of opioid analgesics

for pain management with patients with an addictive disease. The article focuses on specific policy barriers and recent policy initiatives that may improve the use of controlled substances to treat pain for all patients, including those with addiction. Continuing education credits were earned by those professionals who read the article and responded correctly to a series of questions.

Both articles were placed on our website with special permission from the publishers, and electronic announcements were sent out to our national e-mail distribution lists about their availability.

The *Progress Report Card* and *Evaluation Guide 2003* are the PPSG's key publications for this grant period. As mentioned previously in Question 1, Part 2, further efforts to implement our communications strategy occurred after the grant's timeframe, but recent dissemination efforts and interests in these products have so far been successful.

FINAL GRANT REPORT

BIBLIOGRAPHY

**“PAIN RELIEF AND PUBLIC POLICY:
PROFILE OF A NATION”**

TARGETED END-OF-LIFE PROJECTS INITIATIVES

**GRANT # 043412
MAY 1, 2002-AUGUST 31, 2003**

**SUBMITTED
OCTOBER 3, 2003**

**PAIN & POLICY STUDIES GROUP
406 SCIENCE DR., SUITE 202
MADISON WI 53711-1068
608.263.7662
PPSG@MED.WISC.EDU**

BIBLIOGRAPHY

Books and Reports

The Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card*. Madison, Wisconsin: Pain and Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2003. Also available on our website www.medsch.wisc.edu/painpolicy

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Articles

Dahl JL, Bennett ME, Bromley MD, Joranson DE. Success of the State Pain Initiatives. *Cancer Pract* 2002; 10(Suppl. 1):S9-S13. Also appears at www.aacpi.org/images/SPI_article.pdf

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Gilson AM, Ryan KM, Joranson DE, Dahl JL. A reassessment of trends in the medical use and abuse of opioid analgesics. In review.

Poster Presentation

Maurer MA, Gilson AM, Joranson DE, Ryan KM, & Jorenby JP. Changes in state pain policies related to the use of controlled substances for pain management. Presented at the 22nd Annual Scientific Meeting of the American Pain Society; Chicago, IL; March 20-23, 2003.

Presentations and Testimony

David E. Joranson, "Relieving Pain While Preventing Diversion," at the 2002 American Psychiatric Annual Meeting, Philadelphia, Pennsylvania, May 21, 2002.

David E. Joranson, "Regulation of Controlled Prescription Drugs: The Search for Balance," at The International Conference on Pain & Chemical Dependency, New York, New York, June 6, 2002.

David E. Joranson, "Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change," at The Problem of Pain in Medicine, Culture, and Public Policy meeting, Rutgers State University of New Jersey, New Brunswick, New Jersey, June 7, 2002.

David E. Joranson, "Regulatory Overview," at the American Cancer Society Mid-Atlantic Division's meeting on Pain Policy Issues, Richmond, Virginia, June 12, 2002.

David E. Joranson, "Will My Pain Be Managed?" at The Vision vs. The Reality listening conference of the National Association of Attorneys General's Presidential Initiative on End-of-Life Care, Overland Park, Kansas, September 26-28, 2002.

David E. Joranson, "Politics and Policy 101," at the Making Community Connections meeting of the Rallying Points Regional Conference, Chicago, Illinois, November 7-8, 2002.

David E. Joranson, "Will My Pain Be Managed," at The Vision vs. The Reality listening conference of the National Association of Attorneys General's Presidential Initiative on End-of-Life Care, San Diego, California, February 20-21, 2003.

David E. Joranson, "Regulatory Issues [Progress in Achieving Balanced Pain Policies]," at the 5th Annual Eliminating Cancer Pain in the 21st Century meeting, Austin, Texas, February 22, 2003.

David E. Joranson, "Drug Availability for Pain and Symptom Control," at the White House meeting for Palliative Care and the HIV/AIDS Global Pandemic, Washington, District of Columbia, February 25, 2003.

David E. Joranson, Aaron M. Gilson, "The Role of Policy in Improving Pain Management in New Jersey," at the New Jersey Pain Management Policy Advisory Council, Trenton, New Jersey, March 5, 2003.

David E. Joranson, Aaron M. Gilson, "Promoting Pain Relief by Improving Public Policy and Communications," at the American Cancer Society's New England Government Relations & Advocacy Staff Conference, Framingham, Massachusetts, March 6, 2003.

David E. Joranson, "Recent Changes in Regulatory Policy: In Pursuit of 'Balance'," at the 22nd Annual Scientific Meeting of the American Pain Society, Chicago, Illinois, March 20-23, 2003.

David E. Joranson, "Achieving Balance: Preventing Diversion, Ensuring Availability," at the Connecticut Pain Summit and Working Session, Framingham, Massachusetts, March 31, 2003.

David E. Joranson, "Pain Policy in Massachusetts: Where we are and how to plan for the future," at the Massachusetts Pain Initiative Meeting, Auburn, Massachusetts, April 1, 2003.

David E. Joranson, "Are State Pain Policies and Diversion Efforts Balanced," at the Memorial Sloan-Kettering Pain & Palliative Care Grand Rounds, New York, New York, May 1, 2003.

David E. Joranson, "Update: Achieving Balanced State Pain Policies," at the Updates on the Clinical pharmacology of Opioids with Special Attention to Long-Acting Drugs meeting, New York, New York, May 3-4, 2003.

David E. Joranson, "Addressing Regulatory Barriers as Part of Excellent Practice," at the Vital Partnerships in Palliative Care: Toward an Integrated Model conference, Evanston, Illinois, May 9, 2003.

David E. Joranson, "Balance the War on Drugs with Efforts to Relieve Pain," at the Donald W. Benson Lectureship on Pain Management meeting, Baltimore, Maryland, June 4, 2003.

David E. Joranson, "Regulation of Pain Medications," at the Food and Drug Law Institute's Conference on U.S. Drug Enforcement Administration (DEA): Working with DEA – The Other Drug Regulatory Agency, Washington, District of Columbia, June 11-12, 2003.

David E. Joranson, "Pain and the Law," at the 14th Annual Meeting of the American Alliance of

Cancer Pain Initiatives, Pasadena, California, June 12-14, 2003.

David E. Joranson, "Risk of Regulatory Scrutiny: What to Tell Clinicians?" at the National Initiative on Pain Control meeting, Chicago, Illinois, August 4, 2003.

David E. Joranson, Martha A. Maurer, & Matt Bromley. "Making the Grade: A Progress Report Card on State Pain Policies," at the 14th Annual Meeting of the American Alliance of Cancer Pain Initiatives, American Alliance of Cancer Pain Initiatives, Pasadena, California, June 12-14, 2003.

Aaron M. Gilson, "Making the Grade: A Progress Report Card on State Pain Policies," at Fast-Forward: A National Conference for End-of-Life Coalition Leaders, Kansas City, KS; June 4, 2003.

Karen M. Ryan, "An Environment of Increasing Abuse of Opioid Analgesics: What is the Relevance of Pain Policy?" at meeting of the Hospice Directors of Wisconsin, Madison, WI, May 9, 2003.

Aaron M. Gilson, Advisor at Methadone Associated Mortality: A National Assessment Workshop. Substance Abuse and Mental Health Services Administration: U.S. Department of Health and Human Services, Arlington, VI, May 8-9, 2003.

World Wide Web Sites

www.medsch.wisc.edu/painpolicy

Provides full text of individual state pain policies and pain related federal policies, links to other pain organizations, a glossary of terms and full text of articles published by the PPSG. Madison, WI: Pain & Policy Studies Group. Estimated over 10,000 visits per month, compared to 5,862 visits per month in early 2002.

Press Kits and News Releases

An e-mail news release regarding the PPSG director, David Joranson's, receipt of the second Marie Nyswander Humanitarian Award was broadcasted to 10 individuals engaged in communications activities for their respective organizations on July 15, 2002.

An e-mail news release on "North Carolina, pain management and end-of-life care: Communicating the policy" and "U.S. Policies Relevant to the Prescribing of Opioid Analgesics for the Treatment of Pain in Patients with Addictive Disease" was disseminated to 460 academic leaders, pain management advocates, newsletters, professional societies and listserves on December 18, 2002.

An e-mail news release on a communication from the U.S. Drug Enforcement Administration

(DEA) to Dr. Howard Heit and David Joranson providing clarification on the issue of writing more than one prescription for a controlled substance at a time was broadcasted to 460 academic leaders, pain management advocates, newsletters, professional societies and listserves on March 4, 2003.

An e-mail news release on the upcoming release of "*Achieving Balance in State Pain Policy: A Progress Report Card*" was disseminated to 20 academic leaders and pain management advocates on August 27, 2003.

Print Coverage

"A Father's Death, A Daughter's Legacy," in *Health*, May 2002.

"Opioid Diversion: A Renewed Call for a Balanced Drug Policy," in *State Initiatives in End-of-Life Care*, Issue 14, May 2002.

"Grantee Profile: The Pain and Policy Studies Group," in *PDIA Newsletter*, Summer 2002/.

"Knowledge Gap Causes Inadequate Treatment of Chronic Pain," in *The Quality Indicator, Pharmacy Resource*, July 2002.

"Assisted suicide? Pain control? Where's the line?" in *Medical Economics*, October 11, 2002.

"Pain Policy and Pain Management: Strengthening a Delicate Balance," in *Partners Against Pain*, Special Issue, Fall 2002.

"State given poor marks for treatment of the dying," in *Wisconsin State Journal*, November 18, 2002.

"Set your sites on...", in *Pain Matters: Partners Against Pain Magazine*, October 2002.

"State Medical Boards: Encourage Pain Management, Prevent Diversion," in *Pain Matters: Partners Against Pain Magazine*, October 2002.

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"Using Data to Drive Reform – Spotlight on West Virginia," in *State Initiatives in End-of-Life*

Care, Issue 18, February 2003.

“Oral Opioid Therapy for Chronic Peripheral and Central Neuropathic Pain,” reference several articles written by the PPSG in *The New England Journal of Medicine*, March 27, 2003.

“Pain Control: Did Dr. Lewis Cross the Line?” in *Medical Economics*, March 7, 2003.

Television Coverage

WISC-TV, Madison, WI, November 18, 2002

World Wide Web Coverage

“Director of Pain and Policy Studies Group Wins Humanitarian Award,” in *Last Acts E-Newsletter*, July 29, 2002 (listserve).

“PPSG Article on State Med Board Communication Efforts,” in *Cancer Pain Forum: AACPI Update E-Newsletter*, January 16, 2003 (listserve).

“Article Reviews Government Policies Regarding Prescribing of Opioid Analgesics for Pain in Patients with Addictive Diseases,” in *Cancer Pain Forum: AACPI Update E-Newsletter*, March 17, 2003 (listserve).

“DEA Clarifies Regs on Prescribing Practices,” in *Cancer Pain Forum: AACPI Update E-Newsletter*, March 17, 2003 (listserve).

“Article Reviews Policies On Opioid Use for Patients with Addictive Diseases,” in *Cancer Pain Forum: AACPI Update E-Newsletter*, April 16, 2003 (listserve).

“Massachusetts Pain Initiative Moves Forward,” in *Cancer Pain Forum: AACPI Update E-Newsletter*, April 16, 2003 (listserve).

“The American Alliance of Cancer Pain Initiatives Statement on State Prescription Monitoring Programs,” @ www.aacpi.wisc.edu.

“Media Alert - National Pain Experts and Leaders Convene in Pasadena, CA,” @ www.aacpi.wisc.edu.

Sponsored Workshops

“Pain Forum,” November 19, 2002 at Washington Hilton in Washington, District of Columbia. Attended by DEA officials, state medical board members, health care providers, pain organizations.

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/3
EOL

April 14, 2003

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #043412 - Approval of Extension Request

Dear Mr. Joranson:

This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative.

We have reviewed your extension request for the period May 1, 2002, through April 30, 2003 and approved it June 30, 2003. Enclosed is a copy of your financial reporting form with your approved budget of \$200,450 for use when reporting expenditures for the above-mentioned period.

Your final financial and narrative reports are due July 31, 2003.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,



Sophia Kounelias
Financial Analyst

/SXX
Enclosure

cc: Robert C. Andresen
Rosemary Gibson

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

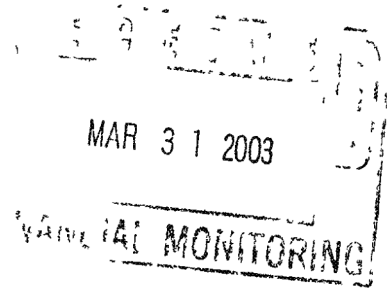
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PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

March 24, 2003



Sophia Kounelias, Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Post Office Box 2316
Princeton, NJ 08543-2316

Reference: RWJF # 043412, Pain Relief and Public Policy: Profile of a Nation
UW # 133-EU26

Dear Ms. Kounelias:

I am writing to request a no-cost extension from April 30, 200² to June 30, 200² for the above referenced grant. Our work on the Report Card on State Pain Policies and the Annual Review of New State Pain Policies is proceeding according to schedule, but we will not be able to have the final product duplicated and distributed by the current April 30 end date. I am requesting the two month extension so that we will have adequate time to duplicate and distribute the final product with the same quality that has gone into its compilation. After we have obtained the final quotes for the production/distribution costs, I will send you a revised budget with narrative for your approval.

Thank you for your assistance.

Sincerely,

A handwritten signature of David E. Joranson.

David E. Joranson
Senior Scientist and Director

Cc: Rosemary Gibson
Research & Sponsored Programs
Medical School
Comprehensive Cancer Center

5/1/02 - 4/03 - 6/30/03
200,450

FINANCIAL REPORT**The Robert Wood Johnson Foundation**

P.O.Box 2316

Princeton, NJ 08543-2316

Phone: (609) 452-8701 Fax: (609) 627-6416

Page: 1

FA: SXK PA: JMS PO: RG

Grantee: *University of Wisconsin-Madison Medical School*

Project Director: David E. Joranson (608-263-7662)

Grant Number: 043412 for [EOL]

Fiscal Officer : Robert C. Andresen (608-262-2896)

Budget Period: May-01-2002 to Jun-30-2003

Grant Period: May-01-2002 to Jun-30-2003

Budget for Year : 1

Revised: Apr-15-2003

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/02-10/02	Period 2 11/02-06/03	Period 3	Period 4	Period 5	Period 6	Total	Variance
PERSONNEL									
Project Director	34,485								
Co-Director	16,490								
Sr. Policy Analyst	18,198								
Policy Analyst	13,142								
Communication Coord.	11,340								
Res. Program Mgr.	9,000								
Program Assistant	5,720								
Office Assistant	2,088								
Fringe Benefits	40,016								
Personnel Subtotal	150,479								
OTHER DIRECT COSTS									
Supplies	2,820								
Duplicating/Printing	3,000								
Postage/Shipping	1,000								
Computer System Support	10,000								
Software	3,620								
Travel	7,980								
Other Direct Subtotal	28,420								
CONSULTANT/CONTRACTUAL	5,000								
Cons/Contrct Subtotal	5,000								
INDIRECT COSTS	16,551								
Grand Total	200,450								

Date Printed
04/23/02

GRANT SIGN-OFF SHEET

I.D.#: 043412

DATE REC'D: April 10, 2002

INST:

University of Wisconsin-Madison Medical School
Madison, WI 53706-1532

TITLE:

National profile of pain relief and public policy

DOLLARS: \$200,450.00

MONTHS: 12

START DATE: 05/01/02

PROJECT DIRECTOR: David E. Joranson

PO: Rosemary Gibson

SO: Doriane C. Miller

CO:

FO: Sophia Kounelias

PA: Jeanne Stives

ANTICIPATED RENEWAL:

RENEWAL EXPECTED: ((YES) NO) ANTICIPATED BOARD DATE: 7/03ESTIMATED DOLLARS: \$200,000 MONTHS: 12

RED FOLDER APPROVAL:

FMO: SXK FINAL DOLLARS: 200,450 FINAL MONTHS: 12TREASURER'S OFFICE: Janice Opalski 200,450 DATE: 4/24/02VP, GEN. COUNS., & SECRETARY: [Signature] DATE: 4/25/02

THE
ROBERT WOOD
JOHNSON
FOUNDATION

1/6
EOL

January 23, 2003

Robert C. Andresen
Administrative Officer
Research and Sponsored Programs
University of Wisconsin-Madison
750 University Avenue, 4th Floor
Madison, WI 53706-1490

Reference: I.D. #043412 - Conveyance of Funds, Guidelines, and Forms

Dear Mr. Andresen:

This supplements our recent award letter in regard to your grant for \$200,450 in support of the Targeted End-of-Life Projects Initiative.

Enclosed with this letter is our check in the amount of \$180,405, which represents 90 percent of your grant award.

The Request for Project Support and Conditions of Grant form imposes a number of specific requirements regarding the use of funds. Since you are responsible for complying with these requirements, I am attaching a copy for your reference. In addition, a copy of our "Grant Budget Revision Guidelines" and "Financial Reporting/Budgeting Practices," to be followed if a budget revision becomes necessary, are also attached. Please read these guidelines and practices carefully.

The Robert Wood Johnson Foundation has initiated a program whereby grantees and contractors are selected at random to receive an internal audit review. The purpose of this review is to: 1) provide the Foundation with the assurance that our funds are being used for their intended purpose; and 2) provide recommendations to our grantees and contractors on methods to improve their organizations. If your organization is selected, you will be notified in advance of the audit.

Final financial and narrative reports on this grant will be due in May 2003. You will receive a reminder in advance of the due date of these reports. We are enclosing the Financial Report form to be completed at the end of the award and returned to the National Program Office with a copy to the Foundation.

Office of the Vice President and Treasurer

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

MDL_RWJF_0000009

When submitting all correspondence under your grant, reference the above-captioned grant number. If someone other than yourself will be the financial contact person on this grant, please supply us with that information. The person who has financial responsibility for your grant at the Foundation is Sophia Kounelias.

If you have any questions about any of the above items, please contact Ms. Kounelias at 609-627-5844. We welcome you to the Foundation's family of grantees and look forward to assisting you.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter Goodwin".

Peter Goodwin
Vice President and Treasurer

/MT
Enclosures

cc: David E. Joranson, M.S.S.W.
Rosemary Gibson ✓

FINANCIAL REPORT
The Robert Wood Johnson Foundation
P.O.Box 2316
Princeton, NJ 08543-2316
Phone: (609) 452-8701 Fax: (609) 627-6416

Page: 1

FA: SXX PA: JMS PO: RG

Grantee: *University of Wisconsin-Madison Medical School*

Project Director: David E. Joranson (608-263-7662)
Fiscal Officer : Robert C. Andresen (608-262-2896)

Grant Number: 043412 for [EOL]
Budget Period: May-01-2002 to Apr-30-2003
Grant Period: May-01-2002 to Apr-30-2003

Budget for Year : 1

Revised:

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/02-10/02	Period 2 11/02-04/03	Period 3	Period 4	Period 5	Period 6	Total	Variance	Pct
PERSONNEL										
Project Director	34,485									
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Policy Analyst	13,142									
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Computer System Support	10,000									
Software	3,620									
Travel	7,980									
Other Direct Subtotal	28,420									
CONSULTANT/CONTRACTUAL	5,000									
Cons/Contrct Subtotal	5,000									
INDIRECT COSTS	16,551									
Grand Total	200,450									

THE
ROBERT WOOD
JOHNSON
FOUNDATION

April 29, 2002

John D. Wiley, Ph.D.
Chancellor
University of Wisconsin-Madison
161 Bascom Hall
500 Linden Drive
Madison, WI 53706

Reference: I.D. #043412

Dear Chancellor Wiley:

It is a pleasure to inform you that The Robert Wood Johnson Foundation has approved a grant of \$200,450 to the University of Wisconsin-Madison Medical School in 12-month continued support of the development of a national profile of pain relief and public policy, under the direction of David E. Joranson, M.S.S.W. This grant is being made under the Foundation's Targeted End-of-Life Projects Initiative.


The funds are to be used in accordance with the proposal to the Foundation and the terms and conditions outlined in the Request for Project Support, dated April 9, 2002. They are also to be used in accordance with the final budget and are to be applied over the period May 1, 2002, through April 30, 2003.

Our Treasurer's Office will be in touch concerning payment of this grant and reporting requirements. During the period of this grant, any questions you may have should be addressed to Rosemary Gibson, who will have responsibility among our staff for this activity.

If your organization wishes to issue a news release on this grant, please feel free to do so. We ask that a copy of the draft text be sent to us for our review and information in advance of dissemination. Please allow three days for this process. Address the copy to the Foundation to the attention of Maureen Cozine in our Communications Department.

All of us at The Robert Wood Johnson Foundation wish you continued success in carrying out this important undertaking.

Sincerely,



Steven A. Schroeder, M.D.

SS:opm

cc: David E. Joranson, M.S.S.W.
Eric Lewandowski
Robert C. Andresen

Office of the President and CEO

Route 1 and College Road East Post Office Box 2316 Princeton, New Jersey 08543-2316 (609) 452-8701

Internet <http://www.rwjf.org>
e-mail: mail@rwjf.org

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B-201

End-of-Life PMT

TARGETED END-OF-LIFE PROJECTS INITIATIVE

Foundation Staff: Rosemary Gibson, Sophia Kounelias, Michelle Larkin, Victoria Weisfeld, Jeanne Stives, Doriane Miller

SUMMARY

Purpose: To support projects under \$1 million that will advance the Foundation's strategic objectives to improve care at the end of life

Total Authorizations: \$34.525 million (since January 1998)

Most Recent Authorization: \$5 million for one year (January 2002)

Program Status: \$31,076,448 expended for 97 grants for the program and \$103,859 expended for 2 program-related expenses that draw down from the authorization (includes grants reported below)

\$3,344,693 remaining in authorization

I. Award of three program grants, totaling \$653,470

DEVELOPING CONSENSUS ON TRENDS TO BE TRACKED FOR AN END-OF-LIFE CARE CHARTBOOK

Award: \$53,580

Duration: Nine months (4/1/02 - 12/31/02)

Brown University Center for Gerontology & Health Care Research

I.D. 44324

TRAINING HEALTH CARE PROVIDERS IN END-OF-LIFE CARE FOR MINORITY POPULATIONS

Award: \$399,440

Duration: 24 months (7/1/02 - 6/30/04)

Memorial Sloan-Kettering Cancer Center, New York, New York

I.D. 38174

B-202

NATIONAL PROFILE OF PAIN RELIEF AND PUBLIC POLICY

Award: \$200,450

Duration: 12 months (5/1/02 - 4/30/03)

Previous Support: \$998,000 for 33 months (8/1/99 - 4/30/02) (I.D. 36509)

University of Wisconsin-Madison Medical School

I.D. 43412

Brown University Center for Gerontology & Health Care Research. This project provides funds to develop a consensus on measures to chart end-of-life care in the US. Ten national experts with knowledge in specific areas of end-of-life care and its measurement will be convened to: (1) review existing and proposed new measures and data sources and assess how well they allow changes to be charted and identify further opportunities for improvement; (2) develop a consensus on a set of feasible and affordable measures to chart changes in end-of-life care in the US; and (3) provide the basis for a white paper that will propose an initial set of measures for a chartbook on end-of-life care and a research agenda to strengthen the tools for measuring the quality of end-of-life care. Joan M. Teno, M.D., Associate Professor of Community Health at Brown University Center for Gerontology & Health Care Research, is the project director.

Memorial Sloan-Kettering Cancer Center. This project will support the development of the Memorial Sloan-Kettering Cancer Center (MSKCC) and North General Hospital (NGH) Palliative Care Collaboration. The Collaboration will: (1) conduct a joint education and training program in palliative care for staff and trainees of NGH and MSKCC; (2) undertake educational interventions for health care providers in the Harlem community; (3) establish an observership program at NGH that will offer minority health professionals in particular an opportunity to spend a one- to two-week period in residence at the palliative care program; and (4) work with community pharmacists to reduce barriers to patients obtaining prescription drugs for the treatment of pain. Richard Payne, M.D., Chief of the Pain and Palliative Care Service at MSKCC, serves as project director.

University of Wisconsin-Madison Medical School. State and federal policies affect the use of opioid analgesics for the treatment of pain. This project will provide continued support for ongoing and balanced analysis of changes that are occurring in states' pain policies as they affect the availability of controlled substances for the treatment of pain. Project staff will: (1) undertake an annual review of new state pain policies and update the Pain and Policy Studies Web site; (2) prepare a report card on state pain policies, as well as maps illustrating trends in policies and opioid consumption in the states; and (3) provide technical

B-203

assistance to states and leading national organizations, such as the American Cancer Society, American Medical Association, American Pain Society, and other groups. The project director is David E. Joranson, Senior Scientist and Director of the Pain and Policy Studies Group at the University of Wisconsin-Madison Medical School.

II. Award of two communications grants, totaling \$467,356

INNOVATIONS IN END-OF-LIFE CARE, AN ONLINE JOURNAL

Award: \$387,356

Duration: 12 months (4/1/02 - 3/31/03)

Previous Support: \$572,078 for 12 months (4/1/01 - 3/31/02) (I.D. 41961)

\$467,806 for 12 months (4/1/2000 - 3/31/01) (I.D. 38962)

\$383,275 for 12 months (4/1/99 - 3/31/2000) (I.D. 36037)

Education Development Center, Inc., Newton, Massachusetts

I.D. 44641

PRODUCTION AND DISTRIBUTION OF END-OF-LIFE MATERIALS FOR LATINOS

Award: \$80,000

Duration: 12 months (5/15/02 - 5/14/03)

Radio Bilingue, Inc., Fresno, California

I.D. 44457

Education Development Center, Inc. (EDC). This grant renews Foundation support for *Innovations in End-of-Life Care*, an online journal. In addition to producing the bimonthly issues on key topics, much of the content of the journal also appears in the print *Journal of Palliative Medicine*. Taking advantage of the recommendations in a business plan prepared under the grantee's current grant, EDC will increase efforts to generate revenues and underwriting from non-RWJF sources this year. Mildred Z. Solomon, Ed.D., Vice President and Director of the Center for Applied Ethics and Professional Practices at EDC, continues as project director.

Radio Bilingue, Inc. This project will develop a radio campaign geared toward changing the way Latinos are cared for at the end of their lives. The campaign has several objectives—increasing awareness and understanding in the Latino community of the personal and social costs associated with futile care and of the alternatives available; improving communications among Latino patients and their

families facing terminal illnesses, and among patients/families/physicians, in order to improve decision making; and educating the Latino community concerning end-of-life issues. Radio Bilingue has a track record of providing meaningful health information and programming for an audience that relies on Spanish and may not be literate in either English or Spanish. Specifically, this project will: produce 12 talk shows, 12 educational messages, 12 promotional messages, 4 mini-dramas, 4 remote broadcasts, 1 roundtable discussion, and 6 feature stories; air each production on all of its 5 network stations (900 airplays) and encourage subscribers to the satellite-distributed talk shows to air them; encourage partnerships between radio stations and hospices in the communities where the programming is aired; and provide a toll-free number to be manned by a bilingual individual with the aid of the California Hospice Foundation. Other co-funders include the Open Society Institute and the Nathan Cummings Foundation. Radio Bilingue itself is providing substantial in-kind support. Samuel Orozco, News and Information Director at Radio Bilingue, is the project director.

III. Award of one research and evaluation contract

ASSESSMENT OF LAST ACTS (PHASE II) AND RALLYING POINTS

Award: \$400,000

Duration: 33 months (6/1/02 - 2/28/05)

George I. Balch, Ph.D., d/b/a Balch Associates, Oak Park, Illinois

Program Contract – I.D. 40500

This project is to conduct an assessment of Last Acts (LAX) (Phase II) and Rallying Points (RP) and to learn how this kind of social change effort functions and how it might relate to social change efforts on other issues. The project will address such issues as what has changed in end-of-life care and planning, and how these changes have been influenced by LAX or RP; what end-of-life ideas, products, services, and practices have changed that are associated with LAX and RP; and how RP and LAX are being leveraged to improve end-of-life care. George I. Balch, Ph.D., Principal of Balch Associates, serves as project director.

July 24-25, 2002

drug abuse mentions decreased from 5.1% to 3.8%. Reports of abuse decreased for meperidine (39%; 1335 to 806), oxycodone (29%; 4526 to 3190), fentanyl (59%, 59 to 24), and hydromorphone (15%; 718 to 609), and increased for morphine (3%; 838 to 865).

Conclusions The trend of increasing medical use of opioid analgesics to treat pain does not appear to contribute to increases in the health consequences of opioid analgesic abuse.

JAMA. 2000;283:1710-1714

Unrelieved pain, whether due to trauma, surgery, cancer or noncancer conditions, and including pain occurring at the end of life, continues to be a major public health concern.¹⁻⁴ Although numerous nonpharmacologic treatments can be used to relieve pain, the use of opioids in the class of morphine is the cornerstone of pain management.⁵⁻⁸

However, because opioids have the potential to be abused, they are regulated under international and national narcotics and controlled substances laws.^{9, 10} International and US federal drug laws embody a dual imperative to ensure the availability of controlled substances for medical and scientific purposes, while at the same time to prevent their diversion and abuse.¹¹

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Concerns related to drug abuse permeate efforts to treat pain with opioids. Patients are concerned about becoming addicted to opioids.^{6, 12, 13} Health care professionals may be reluctant to prescribe, administer, dispense, or stock controlled substances for fear of causing addiction or contributing to the drug abuse problem.¹⁴⁻¹⁷ There are few studies of the extent to which prescription opioid analgesics contribute to the national drug abuse problem.¹⁸ In this descriptive study, we examine the abuse of opioid analgesics in relationship to their medical use.

METHODS

We evaluated abuse trends for opioid analgesics as a class, as well as the medical use and abuse of 5 specific Schedule II opioids: fentanyl, hydromorphone, meperidine, morphine, and oxycodone. We chose these 5 drugs because they are effective in treating severe pain and are marketed as analgesics.^{5-7, 19} We excluded opioid analgesics classified in lower schedules (ie, Schedules III and IV), such as hydrocodone and codeine combinations because they are not indicated for severe pain. We also excluded opioid analgesics for which consumption data would include amounts used for other major indications (such as codeine for cough and diarrhea, and drugs used for treatment of opioid addiction such as methadone).

Data on Drug Abuse Trends

We used the Drug Abuse Warning Network (DAWN) as the source

for data on opioid abuse. DAWN, sponsored by the Substance Abuse and Mental Health Services Administration in the US Department of Health and Human Services, provides estimates of the health consequences of the nonmedical use of individual drugs. It is a large-scale, ongoing retrospective survey of medical records that is used to monitor national drug abuse trends. The system collects information from DAWN-affiliated hospital emergency departments (EDs) to identify substances that are abused, monitor drug abuse patterns and trends and detect new drug entities and combinations; assess health hazards associated with drug abuse; and provide data for national, state, and local drug abuse policy and program planning.

Data are collected on patients 6 years and older from the EDs of approximately 500 US hospitals in 21 metropolitan and other nonmetropolitan areas. Hospitals eligible to participate in DAWN are nonfederal, short-stay general hospitals with 24-hour EDs that are located in the coterminous United States. DAWN has been in existence since 1972, and began collecting data from a nationally representative sample of EDs in 1990.^{20, 21} For our analysis, we used data from the 7-year period from 1990 to 1996 (the most recent year for which data were available at the time this study was begun).

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Each hospital has a designated reporter, usually a member of the ED or medical records department, who is responsible for obtaining information from medical records each time a patient visits the ED with a presenting problem related to drug use; each visit is defined as an episode. Reported episodes typically involve drug overdoses, but also may be the result of long-term drug use and adverse reactions. The reporter collects information for each episode, including gender, ethnicity, age, concomitant use of other drugs, motive for use, reason for ED contact, source of substance, dosage form, and route of administration. The national estimates of abuse are derived from these data. Standardized procedures are used to collect DAWN data; however, there may be some variability from facility to facility.²⁰

Drug abuse in the DAWN system is defined as the nonmedical use of a substance for psychic effect, dependence, or suicide attempt or gesture. Drug abuse can involve the use of illicit drugs or any other substance (eg, heroin, marijuana, peyote, glue, aerosols); prescription drugs in a manner inconsistent with accepted medical practice; and over-the-counter drugs contrary to approved labeling.²⁰

For each episode of drug abuse, as many as 4 different substances, in addition to alcohol, can be recorded. Each is referred to as a drug mention. More than half of DAWN episodes involve multiple drug mentions.²⁰ If DAWN reporters are not able to classify a drug, these mentions are classified as other/unspecified. DAWN reports do not include information about drugs for which the frequency of annual mentions is less than 200. However, for our study, the Substance Abuse and Mental Health Services Administration performed a special data run to extract annual abuse mentions for one of the study drugs, fentanyl, for which the number of mentions is consistently less than 200 per year.

We renamed several drug categories and reclassified a number of drugs to reflect current medical terminology and pharmacology. The

categories designated as narcotic analgesics and nonnarcotic analgesics were renamed as opioid analgesics and nonopioid analgesics. Some drugs were reclassified: codeine combinations were recategorized from other drugs to opioid analgesics. Hydrocodone was reclassified from other/unspecified narcotic analgesics to opioid analgesics. Ibuprofen and naproxen were transferred from other drugs to nonopioid analgesics. Methamphetamine and methaqualone, originally classified as amphetamines and nonbarbiturate sedatives, respectively, were moved to the category of illicit drugs. Other/unspecified drugs listed within each subcategory of DAWN reports were aggregated into 1 "other drugs" category.

DAWN reports routinely combine heroin and morphine mentions into a single category, making it impossible to distinguish between the abuse of an illicit drug and an essential pain medication. We requested that the Substance Abuse and Mental Health Services Administration separate morphine from the heroin-morphine category for the period from 1990 to 1996. Morphine mentions accounted for an annual average of 1.9%, and never exceeded 2.5%, of the combined heroin-morphine category.

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Data on Medical Use of Opioids

We obtained data on medical use of opioids from the US Drug Enforcement Administration's Automation of Reports and Consolidated Orders System (ARCOS) for the years 1990 to 1996. ARCOS is a federal, computerized data system, required by the 1970 Controlled Substances Act.¹⁰ ARCOS monitors the lawful distribution of controlled substances in Schedules I and II and narcotic substances in Schedule III from manufacturers to the retail level of consumption, including hospitals, pharmacies, and licensed practitioners. The Drug Enforcement Administration makes reports on ARCOS data, providing information on individual states and national totals.²² Information is provided for each drug in total grams and grams per 100,000 population.^{23, 24} ARCOS is the only nonproprietary source of information on medical use of opioids.

RESULTS

The percentage of 1996 total DAWN ED mentions represented by each of the 5 drug categories is shown in Table 1. Mentions for opioid analgesics account for less than 4% of total DAWN mentions, mentions for nonopioid analgesics account for 8.6%, and mentions for illicit drugs account for 33.2%. Table 2 presents the abuse levels for the same drug categories as number of mentions and as a percentage of total DAWN mentions for the period 1990 to 1996. From 1990 to 1996, the number of mentions for drug abuse in DAWN increased from 635,460 to 907,561 (42.8% increase), with an increase in total mentions for all drug categories. For opioid analgesics, the total number of mentions increased from 32,430 in 1990 to 34,563 in 1996 (6.6% increase), but declined as a percentage of total mentions from 5.1% in 1990 to 3.8% in 1996. Illicit drugs is the only category of drug abuse that exhibited a continual increase in both number of mentions and percentage of total mentions over the study period.

Trends in the medical use of the 5 selected opioid analgesics from 1990 to 1996 are shown in Table 3. Substantial increases were observed in use of fentanyl and morphine, which occurred in both total use and use adjusted for population.

Table 4 presents trends for the abuse of the 5 selected opioid analgesics for the same 7-year trend. The number of abuse mentions, as measured by DAWN, for fentanyl, hydromorphone, meperidine, and oxycodone declined during the study period, whereas abuse mentions for morphine increased by 3.2%. The abuse levels for each of the 5 opioid analgesics, as a percentage of total DAWN mentions, were less than 1% and declined during the study period despite substantial increases in medical use.

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Official Drug Enforcement Administration data indicate that the amounts of fentanyl, oxycodone, hydromorphone, and morphine distributed to the retail level have increased substantially.²⁵ According to the World Health Organization, increasing medical use of opioids is one indication that progress is being made to improve pain management.¹⁹ Despite these increases, pain is still inadequately treated due to numerous barriers to pain management.^{6, 26} In the future, as these barriers are addressed, the medical use of opioid analgesics may be expected to increase further.

In this study, meperidine was the only opioid that decreased in medical use over the study period. This decrease may reflect increasing awareness of the shortcomings of the use of meperidine for chronic pain, which includes short duration of action and accumulation of a long-lived toxic metabolite.^{6, 27}

These data suggest that opioid analgesics, including the 5 study drugs, are a relatively small part of drug abuse as measured by the DAWN system. Although there are year-to-year variations, the abuse levels have remained low and relatively stable for the past 7 years despite substantial increases in the medical use of opioids. Although abuse of most opioids decreased during the study period, several caveats are needed to place these results in context.

First, these data also indicate that there is some abuse of opioid analgesics. However, compared with the abuse of other drugs, illicit drugs in particular, the abuse of opioid analgesics appears to be relatively low, accounting for 3.8% of total DAWN mentions in 1996. Moreover, even though there were increases in the total number of mentions of abuse for opioid analgesics during the study period, the proportion of mentions for opioid abuse relative to total reports of drug abuse decreased by 25% (from 5.1% to 3.8%).

Second, the DAWN system may underestimate the extent of the drug abuse problem. The DAWN system measures only those episodes of drug abuse that result in an admission to an ED, and thus underreports the true extent of all drug abuse, such as drug-

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Fourth, we used data on abuse of opioids from the DAWN system. Two other sources of drug abuse information were considered but not used. The National Household Survey on Drug Abuse,²⁸ a widely known survey measuring drug abuse prevalence, was not used because data are not available for specific opioid analgesics. Also, the Toxic Exposure Surveillance System,²⁹ which tracks exposures to toxic substances from a large sample of regional poison control centers, was not used because it is not nationally representative and because the cost of acquiring the data was prohibitive.

4/19/00

Author/Article Information

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Author Affiliations: Department of Pharmacology (Dr Dahl) and the Pain and Policy Studies Group, Comprehensive Cancer Center (Mr Joranson, Ms Ryan, and Dr Gilson), University of Wisconsin Medical School, Madison.

Corresponding Author and Reprints: David E. Joranson, MSSW, Pain and Policy Studies Group, 1900 University Ave, Madison, WI 53705 (e-mail: joranson@facstaff.wisc.edu).

Financial Disclosures: Mr Joranson receives honoraria from Knoll Pharmaceutical, Purdue Pharma, and Janssen Pharmaceutical. He also receives unrestricted grants from Knoll Pharmaceutical and Purdue Pharma and is a consultant for Purdue Pharma. Dr Dahl serves on the Speakers Bureau for Purdue Pharma and is a consultant for Knoll Pharmaceuticals.

Funding/Support: This research was supported by grant 031461 from the Robert Wood Johnson Foundation.

Acknowledgment: We are grateful for the assistance from the Office of Applied Studies, the Substance Abuse and Mental Health Services Administration, and the US Drug Enforcement Administration, Office of Diversion Control, Drug Operations Section.

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University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

45312
1/9
EOL

April 19, 2002

RECEIVED

APR 26 2002

THE ROBERT WOOD JOHNSON
FOUNDATION

The Robert Wood Johnson Foundation
Jeanne M. Stives
P.O. Box 2316
Princeton, NJ 08543-2316

In reply please refer to:
Proposal #88728

Dear Ms Stives:

Please accept this letter as authorization for Janice H. Calvin, Administrative Officer, Research & Sponsored Programs to sign on my behalf.

Sincerely,

A handwritten signature in cursive script, appearing to read "Eric Lewandowski".

Eric Lewandowski
Non-Federal Director
Research & Sponsored Programs

cc: file



THE ROBERT WOOD JOHNSON
FOUNDATION

APR 10 2002

ANSWERED	RECORDED	DATA SHEET
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University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

April 9, 2002

The Robert Wood Johnson Foundation
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
Proposal #88728

To Whom It May Concern:

On behalf of the Board of Regents of the University of Wisconsin System, we are submitting a revision to a proposal entitled *Pain Relief and Public Policy: Profile of a Nation* under the direction of David E. Joranson. We are requesting \$200,000.00 for the period of May 1, 2002 through April 30, 2003.

The attached copies of our tax documentation are true and correct copies of the originals on file with the University of Wisconsin System and they remain in full force and effect.

In regards to the recent addition to the Conditions of Grant, Article 13, The University of Wisconsin is an agency of the State of Wisconsin and, as such, subject to the laws of the state. Under Wisconsin law, the State assumes sovereign immunity and, therefore, the University can not agree to the jurisdiction or venue of another state. We request the second sentence of Article 13 be lined out from the Conditions of Grant. Review this modification and if acceptable, please counter-initial on behalf of The Robert Wood Johnson Foundation.

The Chancellor of our organization is: John D. Wiley, Ph.D. Physics, Chancellor, University of Wisconsin, 161 Bascom Hall, 500 Linden Drive, Madison, Wisconsin 53706.

We ask that you use the University's above-referenced proposal in any future correspondence. Questions regarding administrative or contractual matters should be directed to Deb Lapotka at (608) 262-9580 or dlapotka@rsp.wisc.edu. Questions regarding the technical nature of this application should be directed to the Principal Investigator.

Sincerely,

A handwritten signature in black ink, appearing to read "Janice H. Kalvin".

Janice H. Kalvin
Administrative Officer

Enclosures

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page <http://www.rsp.wisc.edu>

MDL_RWJF_0000009

THE
ROBERT WOOD
JOHNSON
FOUNDATION

DO NOT SEPARATE
THIS DOCUMENT

Request for Project Support
and
Conditions of Grant

Route 1 and College Road East
P.O. Box 2316
Madison, WI 53703-2316
THE ROBERT WOOD JOHNSON
FOUNDATION (609) 452-8701

APR 10 2002

Title of Project:

Pain Relief and Public Policy: Profile of a Nation

ANSWERED RECORDED DATA SHEET

Purpose of Project:

The purpose of this project is to develop a report that ranks the state's response to developing a balanced environment for pain management.

Applicant Institution (name of legal entity, address, telephone number, fax number, and e-mail address)

~~University of Wisconsin~~
~~The Board of Regents of the Univ of WI Sys.~~
~~Research and Sponsored Programs, 4th Floor~~
750 University Ave.
Madison WI 53706-1490

Tel 608-262-3822
Fax 608-262-5111

nmw
4/25/02

Amount of Support Requested (total project period)

~~\$200,000~~ 200,450

SXIL
4/12/02

Period for Which Support is Requested (total project period)

From May 1, 2002 Through April 30, 2003
Month Day Year Month Day Year

Institution Financial Officer (full name, title, address, telephone number, fax number, and e-mail address)

Robert Andresen
Administrative Officer
Research and Sponsored Programs, 4th Floor
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Madison WI 53706-1490
Tel 608/262-2896
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*Project Director (full name, title, address, telephone number fax number, and e-mail address)

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Tel 608/263/7662
Fax 608/263-0259
joranson@facstaff.wisc.edu

Institutional Approval (full name, title, address, telephone number, fax number and e-mail address of official authorized to sign for institution)

Eric Lewandowski
Non-Federal Director
Research and Sponsored Programs, 4th Floor
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Madison WI 53711-1068
Tel 608/262-0152
Fax 608/262-5111 elewandowski@rsp.wisc.edu

(NOTE Signature required on page 4)

(NOTE Signature required on page 4)

Please provide the following evidence, as applicable, of your institution's tax status:

If your institution is a tax-exempt organization described in Section 501(c)(3) of the Internal Revenue Code, (i) a copy of the letter your institution received from the Internal Revenue Service stating that your institution is exempt from taxation by virtue of being described in Section 501(c)(3); (ii) a copy of the letter your institution received from the Internal Revenue Service stating that either your institution is not a private foundation described in Section 509(a) or stating that your institution is an exempt operating foundation described in Section 4940(d)(2); and (iii) a copy of Form 4653 and other data, if any, your institution has filed with or received from the Internal Revenue Service concerning your tax status

If your institution is an organization described in Section 170(c)(1) or Section 511(a)(2)(B) of the Internal Revenue Code, (i) a copy of the correspondence, if any, from the Internal Revenue Service stating that fact, or (ii) a copy of the legislation establishing your institution.

These documents must be accompanied by a letter signed by a responsible officer of the institution certifying that the copies provided are true and correct copies of the originals on file with the institution and that they remain in full force and effect.

Any questions you may have about your tax-exempt status should be directed to the Office of the Vice President, General Counsel and Secretary (609-243-5922).

*The project director is the individual who will be directly responsible for developing the proposed activity, its implementation, and day-to day direct supervision of the project should a grant be awarded

RWJF (7/2000)--PUBLIC ENTITIES AND EXEMPT OPERATING FOUNDATIONS DESCRIBED IN SECTION 4940(d)(2) OF THE INTERNAL REVENUE CODE

MDL_RWJF_0000009

CONDITIONS OF GRANT

Following are the conditions applying to grants made by The Robert Wood Johnson Foundation ("the Foundation"). You should read these conditions carefully prior to signing this form. Your signature on this form constitutes your acceptance in full of all conditions contained herein. To induce the Foundation to make the grant requested hereby, you ("the grantee") accept and agree to comply with the following conditions in the event that such grant is awarded. As used throughout this form, the term "grant" shall include the income, if any, arising therefrom unless the context otherwise requires.

1. **PURPOSE AND ADMINISTRATION.** The grant shall be used exclusively for the purposes specified in the grantee's proposal, dated _____, the Request for Project Support Form on page 1 hereof, and related documents, all as approved by the Foundation.

The grantee will directly administer the project or program being supported by the grant and agrees that no grant funds shall be disbursed to any organization or entity, whether or not formed by the grantee, other than as specifically set forth in the grant proposal referred to above.

2. **USE OF GRANT FUNDS.**

- A. No part of the grant shall be used to carry on propaganda or otherwise attempt to influence legislation within the meaning of Section 4945(d)(1) of the Internal Revenue Code.
- B. No part of the grant shall be used to attempt to influence the outcome of any specific public election or to carry on, directly or indirectly, any voter registration drive within the meaning of Section 4945(d)(2) of the Internal Revenue Code.
- C. No part of the grant shall be used to provide a grant to an individual for travel, study, or similar purpose within the meaning of Section 4945(g) of the Internal Revenue Code, without prior written approval of the Foundation. Payments of salaries, other compensation, or expense reimbursement to employees of the grantee within the scope of their employment do not constitute "grants" for these purposes and are not subject to these restrictions.
- D. No part of the grant shall be used for a grant to another organization without prior written approval of the Foundation.
- E. No part of the grant shall be used for other than religious, charitable, scientific, literary, or educational purposes or the prevention of cruelty to children or animals within the meaning of Section 170(c)(2)(B) of the Internal Revenue Code.
- F. The grantee promptly shall repay any portion of the grant which for any reason is not used exclusively for the purposes of the grant. The grantee shall repay to the Foundation any portion of the grant which is not used exclusively for the purposes described in Section 1 hereof within the time specified in the grantee's proposal or within any approved extension of said time period within fifteen (15) days after such specified time or such extension. If the Foundation terminates the grant pursuant to Section 10 hereof, the grantee shall repay within thirty (30) days after written request by the Foundation all grant funds unexpended as of the effective date of termination and all grant funds expended for purposes or items allocable to the period of time subsequent to the effective date of termination. If any portion of the grant is used for purposes other than those described in Section 170(c)(2)(B) of the Internal Revenue Code, the grantee shall repay to the Foundation that portion of the grant and any additional amount in excess of such portion necessary to effect a correction under Section 4945 of the Internal Revenue Code.
- G. If the grantee is directly or indirectly controlled by the Foundation or by one or more "disqualified persons" (within the meaning of Section 4946 of the Internal Revenue Code) with respect to the Foundation, the grantee agrees (i) to expend all of the grant prior to the grantee's first annual accounting period following the taxable year in which the grantee receives a grant payment, thereby permitting the Foundation to count the grant as a qualifying distribution under Section 4942(g)(3) and (h), and (ii) to submit to the Foundation promptly after the close of the grantee's annual accounting period a full and complete written report signed by an appropriate officer, director, or trustee, showing that the qualifying distribution has been made, the name and address of the recipient or recipients, the amounts received by each, and that all the distributions are treated as distributions out of corpus.

3. **BUDGET.** The grant budget and any revisions thereto shall comply with the Foundation's Budget Preparation Guidelines, Budget Revision Guidelines, and any additional instructions contained in the Treasurer's letter sent by the Foundation to the grantee (collectively the "Budget Guidelines"). Such Budget Guidelines, as they may be modified by the Foundation from time to time, are incorporated herein by this reference. Expenditures of the grant funds must adhere to the specific line items in the grantee's approved grant budget, and transfers among line items (increases and decreases) are permitted only under the conditions and to the extent indicated in the Budget Guidelines.

4. **ACCOUNTING AND AUDIT.** The grantee shall indicate the grant separately on its books of account. The grantee shall maintain a systematic accounting record of the receipt and disbursement of funds and expenditures incurred under the terms of the grant and shall retain the substantiating documents such as bills,

invoices, cancelled checks, and receipts in the grantee's files for a period of not less than four (4) years after expiration of the grant period. The grantee agrees promptly to furnish the Foundation with copies of such documents upon the Foundation's request.

The grantee agrees to make its books and records available to the Foundation at reasonable times.

The Foundation, at its expense, may audit or have audited the books and records of the grantee insofar as they relate to the disposition of the funds granted by the Foundation, and the grantee shall provide all necessary assistance in connection therewith.

- 5 **REPORTS.** Financial reports shall be furnished by the grantee to the Foundation for each budget period of the grant and upon expiration, repayment (pursuant to Section 2F hereof), or termination of the grant (pursuant to Section 10 hereof). The financial report shall show actual expenditures reported as of the date of the report against the approved line item budget. Annual Progress Reports and Final Grant Reports shall be furnished by the grantee to the Foundation and shall include a report on the progress made by the grantee towards achieving the grant purposes and any problems or obstacles encountered in the effort to achieve the grant purposes. All such reports shall be furnished to the Foundation within a reasonable period of time after the close of the period for which such reports are made. All such reports shall be retained in the grantee's files for a period of not less than four (4) years after expiration of the grant period.

The Foundation may, at its expense, monitor and conduct an evaluation of operations under the grant, which may include visits by representatives of the Foundation to observe the grantee's program procedures and operations and to discuss the program with the grantee's personnel.

6. **COPYRIGHT, FOUNDATION USE OF DATA, AND PUBLIC USE DATA TAPES.** All copyright interests in materials produced as a result of this grant are owned by the grantee. The grantee hereby grants to the Foundation a nonexclusive, irrevocable, perpetual, royalty-free license to reproduce, publish, republish in print or electronic form, including in electronic databases or in any future form not yet discovered or implemented, copy, summarize, condense, abstract or excerpt, or otherwise use and to license others to use any and all such materials which are or will be produced as a result of this grant, including any and all data collected in connection with the grant in any and all forms in which said data are fixed.

The grantee represents and warrants that the material produced by the grantee under this grant is and will be original and does not and will not infringe upon any statutory or common law copyright, proprietary right, or any other right of any other person, and has not heretofore been published or used in any medium for any purpose.

At any time during the period of this grant, at the Foundation's request, the grantee shall, at no additional cost to the Foundation, cause public use data files to be constructed (with appropriate adjustments to assure individual privacy) in accordance with the specifications of the Inter-University Consortium for Political and Social Research, University of Michigan, including the full documentation outlined in the Consortium's current data preparation manual. Unless the Foundation shall otherwise specify, such public use data files shall include all data files used to conduct the analysis under the grant. The grantee shall transmit one computer-readable copy of such public use data files and documentation to the Consortium upon expiration of the grant period.

- 7 **PUBLIC REPORTING.** The Foundation will report this grant, if made, in its next Annual Report. The Foundation does not usually issue press releases on individual grants; however, should the Foundation elect to do so, it would discuss the press release with the grantee in advance of dissemination. The grantee may issue its own press announcement but shall seek approval of the announcement from the Foundation before distribution. In addition, the Foundation may prepare reports on the project or program, briefly describing its accomplishments and results, which may be published and distributed, including posting on the Foundation's Internet site, and used by the Foundation to respond to inquiries and for other public information purposes.

The grantee shall send to the Foundation copies of all papers, manuscripts, and other information materials which it produces that are related to the project supported by the Foundation.

In all public statements concerning the Foundation--press releases, annual reports, or other announcements--the grantee is specifically requested to refer to the Foundation by its full name The Robert Wood Johnson Foundation.

- 8 **GRANTEE TAX STATUS.** The grantee represents that it is currently either (i) a tax-exempt entity described in Section 501(c)(3) of the Internal Revenue Code and either (a) is not a private foundation described in Section 509(a); or (b) is an exempt operating foundation described in Section 4940(d)(2), or (ii) an organization described in Section 170(c)(1) or Section 511(a)(2)(B). The grantee shall immediately give written notice to the Foundation if the grantee ceases to be exempt from federal income taxation as an organization described in Section 501(c)(3) or its status as not a private foundation under Section 509(a), as an exempt operating foundation described in Section 4940(d)(2), or as a Section 170(c)(1) or Section 511(a)(2)(B) organization is materially changed.

- 9 **CERTIFICATION REQUIRED WHEN GRANT MAY BE USED FOR RESEARCH INVOLVING HUMAN SUBJECTS.** If the grant is to be used in whole or in part for research involving human subjects, the grantee hereby certifies that the grantee will conduct the research in compliance with the ethical standards and the

criteria for approval of research set forth in United States Department of Health and Human Services policy for the protection of human research subjects (45 CFR part 46 and related policies and protocols, as amended from time to time).

10. **GRANT TERMINATION.** It is expressly agreed that any use by the grantee of the grant proceeds for any purpose other than those specified in Section 170(c)(2)(B) of the Internal Revenue Code will terminate the obligation of the Foundation to make further payments under the grant.

The Foundation, at its sole option, may terminate the grant at any time if (i) the grantee ceases to be exempt from federal income taxation as an organization described in Section 501(c)(3) of the Internal Revenue Code, (ii) the grantee's status as not a private foundation under Section 509(a), its status as an exempt operating foundation under Section 4940(d)(2), or its status as a Section 170(c)(1) or Section 511(a)(2)(B) organization is materially altered; or (iii) in the Foundation's judgment, the grantee becomes unable to carry out the purposes of the grant, ceases to be an appropriate means of accomplishing the purposes of the grant, or fails to comply with any of the conditions hereof.

If the grant is terminated prior to the scheduled completion date, the grantee shall, upon request by the Foundation, provide to the Foundation a full accounting of the receipt and disbursement of funds and expenditures incurred under the grant as of the effective date of termination.

11. **LIMITATION; CHANGES; SEVERABILITY.** It is expressly understood that the Foundation by making this grant has no obligation to provide other or additional support to the grantee for purposes of this project or any other purposes. Any changes, additions, or deletions to (i) the conditions of the grant, or (ii) the proposal referred to in Section 1, must be made in writing only and must be jointly approved by the Foundation and the grantee. The invalidity in whole or in part of any term or condition of this grant shall not affect the validity of the other terms and conditions

12. **CHANGED CIRCUMSTANCES; REGULATORY ACTION.** The grantee shall promptly notify the Foundation in writing if there is any change in circumstances that might affect the grantee's ability to carry out the grant; the grantee undergoes a merger, division, or other corporate reorganization; the grantee becomes subject to a proceeding under the Bankruptcy Code or other law relating to insolvency or makes an assignment for the benefit of creditors; the grantee becomes subject to an investigation or proceeding brought by the Attorney General, or any other regulatory agency, or the grantee receives notice of any litigation or other legal action relating to the grant or is served with a subpoena or other legal process seeking to compel production of or obtain access to any data related to the grant

13. **GOVERNING LAW; JURISDICTION; VENUE.** This grant shall be governed by the laws of the state of New Jersey. ~~Exclusive jurisdiction and venue over any disputes under this grant shall be in Middlesex County, New Jersey.~~

14. **NON-TRANSFERABILITY; NO JOINT VENTURE.** This grant is not transferable. Nothing contained herein shall be construed in any manner to imply or create a relationship between the Foundation and the grantee as partners, joint venturers, or of agency. The grantee shall not act in any manner as an agent or representative of the Foundation

PLEASE INITIAL
JHK

**Board of Regents of the
University of Wisconsin System
Research & Sponsored Programs
750 University Avenue
Madison, WI 53706-1490**

The foregoing conditions are hereby accepted and agreed to as of the date indicated below.

Date: APR 9 2002

Applicant Institution: Madison, WI 53706-1490

By: 
(Signature of Authorized Official)
Janice H. Kalvin
Administrative Officer

Title: _____

Date: April 9, 2002

By: 
(Signature of Project Director)

Title: Project Director



THE ROBERT WOOD JOHNSON
FOUNDATION

APR 10 2002

ANSWERED	RECORDED	DATA SHEET
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University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

April 9, 2002

The Robert Wood Johnson Foundation
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
Proposal #88728

To Whom It May Concern:

On behalf of the Board of Regents of the University of Wisconsin System, we are submitting a revision to a proposal entitled *Pain Relief and Public Policy: Profile of a Nation* under the direction of David E. Joranson. We are requesting \$200,000.00 for the period of May 1, 2002 through April 30, 2003.

The attached copies of our tax documentation are true and correct copies of the originals on file with the University of Wisconsin System and they remain in full force and effect.

In regards to the recent addition to the Conditions of Grant, Article 13, The University of Wisconsin is an agency of the State of Wisconsin and, as such, subject to the laws of the state. Under Wisconsin law, the State assumes sovereign immunity and, therefore, the University can not agree to the jurisdiction or venue of another state. We request the second sentence of Article 13 be lined out from the Conditions of Grant. Review this modification and if acceptable, please counter-initial on behalf of The Robert Wood Johnson Foundation.

The Chancellor of our organization is: John D. Wiley, Ph.D. Physics, Chancellor, University of Wisconsin, 161 Bascom Hall, 500 Linden Drive, Madison, Wisconsin 53706.

We ask that you use the University's above-referenced proposal in any future correspondence. Questions regarding administrative or contractual matters should be directed to Deb Lapotka at (608) 262-9580 or dlapotka@rsp.wisc.edu. Questions regarding the technical nature of this application should be directed to the Principal Investigator.

Sincerely,

A handwritten signature in dark ink, appearing to read "Janice H. Kalvin".

Janice H. Kalvin
Administrative Officer

Enclosures

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page <http://www.rsp.wisc.edu>

MDL_RWJF_0000009

FROM: RESEARCH ADMIN.-FIN.

TO: DOC-IT

APR 18 1998
THE ROBERT WOOD JOHNSON
FOUNDATION

APR 10 2002

ANSWERED	RECORDED	DATA SHEET
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Internal Revenue Service
Washington, DC 20224

Date:

In reply refer to:

12-24-70

THE UNIVERSITY OF WISCONSIN
1956 VAN HISE HALL 1220 LINDEN DR
MADISON, WI

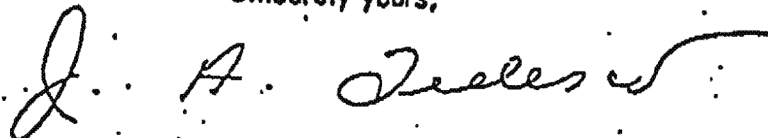
53706

Gentlemen:

Based on the information you recently submitted, we have classified you as an organization that is not a private foundation as defined in section 509(a) of the Internal Revenue Code.

Your classification is based on the assumption that your operations will be as stated in your notification. Any changes in your purposes, character, or method of operation must be reported to your District Director so he may consider the effect on your status.

Sincerely yours,



Chief, Rulings Section
Exempt Organizations Branch

FORM N-0714 (8-70) (CONTINUOUS)

FROM: RESEARCH ADMIN.-FIN.		TO: DOC-IT		APR 16, 1996		9:32AM P.03	
form 1000 (June 1970) Department of the Treasury Internal Revenue Service		Notification Concerning Foundation Status					
Please print or type		Name of organization				Employer Identification Number	
		The University of Wisconsin				39-6006492	
		Number and street					
		1856 Van Hise Hall, 1220 Linden Drive					
		City or town, State and ZIP code					
		Madison, Wisconsin 53706					

Please place an "X" in the one numbered block that applies to your organization, provide any additional information called for, and return the form promptly to the Internal Revenue Service Center, 11601 Roosevelt Boulevard, Philadelphia, Pennsylvania 19155. Do not check a block until you have read the instructions and Code definitions applicable to that block. Section references are to the Internal Revenue Code of 1954.

- 1 ☐ We are a private foundation within the meaning of section 509(a). (If you are a private foundation, are you claiming status as an operating foundation within the meaning of section 4942(j)(3)? ☐ Yes ☐ No If "Yes," attach a statement setting forth all the facts upon which you base your answer including an identification of the clause of section 4942(j)(3)(B) that is applicable.

We are not a private foundation because we are:

- 2 ☐ A church. Section 170(b)(1)(A)(i).

- 3 ☒ A school. Section 170(b)(1)(A)(ii).

- 4 ☐ A hospital. Section 170(b)(1)(A)(iii).

- 5 ☐ A medical research organization operated in conjunction with a hospital. Section 170(b)(1)(A)(iii).

- 6 ☐ A Governmental unit. Section 170(b)(1)(A)(v).

- 7 ☐ An organization operated for the benefit of a college or university owned or operated by a Governmental unit. Section 170(b)(1)(A)(iv).

(Complete the Financial Schedule on page 2.)

- 8 ☐ An organization that normally receives a substantial part of its support from a Governmental unit or from the general public. Section 170(b)(1)(A)(vi).

(Complete the Financial Schedule on page 2.)

- 9 ☐ An organization that normally receives no more than 1/3 of its support from gross investment income and more than 1/2 of its support from contributions, membership fees, and gross receipts from activities related to its exempt function—subject to certain exceptions. Section 509(a)(2).

(Complete the Financial Schedule on page 2.)

- 10 ☐ An organization operated solely for the benefit of and in connection with one or more of the organizations described in 2 through 9 (or for the benefit of one or more organizations described in section 501(c)(4), (5), or (6) and also described in 9 (above), but not controlled by disqualified persons other than foundation managers. Section 509(a)(3).

(Attach a statement identifying and describing the organization(s) for whose benefit you are operated and the relationship between you and the organization(s).)

- 11 ☐ An organization organized and operated to test for public safety. Section 509(a)(4).

- 12 ☐ We are not sure of our classification.

(Attach a copy of your most recently filed information return, Form 990-A, if you filed one, and a statement describing your operations and explaining why you are not sure of your classification. If you think you may be described in 7, 8, or 9, complete the Financial Schedule on page 2.)

I declare that I have examined the information entered on this form, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct and complete. (Must be signed by a principal officer, manager, or authorized trustee of the organization.)

R. H. Lorenz

(Signature)

October 23, 1970

(Date)

Vice President for Business and Finance

(Title)

43412



University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

THE ROBERT WOOD JOHNSON
FOUNDATION

2002

February 12, 2002

ANSWERED	RECEIVED	DATE SHEET
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The Robert Wood Johnson Foundation
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
Proposal #88728

Dear Ladies and Gentlemen:

On behalf of the Board of Regents of the University of Wisconsin System, we are submitting a proposal entitled "Pain Relief and Public Policy: Profile of a Nation" under the direction of David E. Joranson. We are requesting \$245,530.00 for the period of April 1, 2002 through March 31, 2003.

The attached copies of our tax documentation are true and correct copies of the originals on file with the University of Wisconsin System and they remain in full force and effect.

We ask that you use the University's above-referenced proposal in any future correspondence. Questions regarding administrative or contractual matters should be directed to Christy R Wipperfurth at (608) 262-6712. Questions regarding the technical nature of this application should be directed to the Principal Investigator.

Sincerely,

C. wipperfurth@rsp.wisc.
edu

Janice H. Kalvin
Administrative Officer

Enclosure



43412
THE ROBERT WOOD JOHNSON
FOUNDATION

APR 10 2002

ANSWERED	RECORDED	DATA SHEET
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University of Wisconsin-Madison
Graduate School, Research and Sponsored Programs

April 9, 2002

The Robert Wood Johnson Foundation
P. O. Box 2316
Princeton, NJ 08543-2316

In reply, please refer to
Proposal #88728

To Whom It May Concern:

On behalf of the Board of Regents of the University of Wisconsin System, we are submitting a revision to a proposal entitled *Pain Relief and Public Policy: Profile of a Nation* under the direction of David E. Joranson. We are requesting \$200,000.00 for the period of May 1, 2002 through April 30, 2003.

The attached copies of our tax documentation are true and correct copies of the originals on file with the University of Wisconsin System and they remain in full force and effect.

In regards to the recent addition to the Conditions of Grant, Article 13, The University of Wisconsin is an agency of the State of Wisconsin and, as such, subject to the laws of the state. Under Wisconsin law, the State assumes sovereign immunity and, therefore, the University can not agree to the jurisdiction or venue of another state. We request the second sentence of Article 13 be lined out from the Conditions of Grant. Review this modification and if acceptable, please counter-initial on behalf of The Robert Wood Johnson Foundation.

The Chancellor of our organization is: John D. Wiley, Ph.D. Physics, Chancellor, University of Wisconsin, 161 Bascom Hall, 500 Linden Drive, Madison, Wisconsin 53706.

We ask that you use the University's above-referenced proposal in any future correspondence. Questions regarding administrative or contractual matters should be directed to Deb Lapotka at (608) 262-9580 or dlapotka@rsp.wisc.edu. Questions regarding the technical nature of this application should be directed to the Principal Investigator.

Sincerely,

A handwritten signature in black ink, appearing to read "Janice H. Kalvin".

Janice H. Kalvin
Administrative Officer

Enclosures

400 A.W. Peterson Building
750 University Avenue
Madison, WI 53706-1490

Telephone (608) 262-3822
Fax (608) 262-5111
Home Page <http://www.rsp.wisc.edu>

MDL_RWJF_0000009

43412
Final Proposal

Pain Relief and Public Policy: Profile of a Nation

A proposal to the Robert Wood Johnson Foundation

April 8, 2002

Submitted by

David E. Joranson, MSSW
Director
Pain & Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
Madison WI

Introduction

During the last decade in the U.S., public recognition of inadequate pain management and end-of-life care became a matter of public discussion, stimulating a major expansion of education and clinical services, as well as important communications and policy initiatives. The trends that emerged in pain-related policies are without precedent.

State and federal agencies began adopting new laws, regulations and guidelines to encourage pain management, to recognize the use of opioid pain medications, and to address health-care practitioners' concerns about being investigated. In 1989, there were only six very different policies in all the states. By 2001, 46 states had adopted 82 policies, many having similar provisions because they were patterned after models developed with guidance from the Pain & Policy Studies Group (PPSG). The Drug Enforcement Administration and other regulatory agencies embarked on heretofore unheard of engagement with pain and health organizations, formally endorsing guidelines for pain management, including the use of opioid analgesics.

In this grant, we propose to develop a "profile of a nation" that will document and evaluate the progress that has been made in the U.S. relating to policy development and the medical use of opioid analgesics, and will provide new resources and assistance to improve pain policy against a backdrop of increasing concerns about abuse of pain medications. The projects outlined in this proposal build on the research and database capabilities of the PPSG, which are now sufficiently developed to undertake these new and important tasks.

Part 1: Elements of a National Profile

Outline of Projects

- (1) Prepare a report card on state pain policies as well as maps of pain policies and opioid consumption in the states
- (2) Prepare annual review of new state pain policies
- (3) Update state pain policies database

Description of Projects

(1) Prepare a Report Card on State Pain Policies as Well as Maps of Pain Policies and Opioid Consumption in the States. In this project we will develop a report card ranking the states' pain policies, as well as maps and graphics to describe the types of policies that states have, as well as their opioid pain medication consumption statistics.

For the report card we will collect policy data from the states, evaluate it as we did for the PPSG report on federal and state pain policies (the Evaluation Guide)¹, develop a methodology for ranking the states, and present this information in graphic formats. We will present the data in several forms: (1) the ranking of each state, (2) a map of the U.S. showing the states with the most and least positive and negative provisions, (3) a commentary about the central issues involved in states with low and high rankings, and (4) links to resources and models that can be used to improve state pain policy. A low score may lend impetus to groups interested in

¹ Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM *Achieving Balance in Federal and State Pain Policy A Guide to Evaluation* The Pain & Policy Studies Group, University of Wisconsin Comprehensive Care Center 2000

improving state policies to reflect balance. We have begun to develop a method to quantify policy data from the Evaluation Guide, supplemented by an analysis of policies adopted after the Evaluation Guide, so that the states can be compared and ranked. States' scores would serve as a baseline from which to evaluate progress to improve policy as is being done in Michigan, New York and Kansas. States with higher scores would be encouraged to communicate their policies to employees/investigators, licensees and the public in order to promote understanding of the positive regulatory environment that is expressed in state policy. The report card would encourage states to adopt model policy language that is available in order to enhance the regulatory environment for the treatment of pain, while also emphasizing the responsibility to prevent abuse and diversion. The report card would be widely disseminated and publicized according to activities in Part 2 of this proposal.

For the mapping part of this project, we will prepare maps of the U.S., using a graphic database program (such as MapInfo), that describe the status of (1) the states' pain-specific policies, (2) state policies that establish prescription monitoring programs, and (3) states' consumption of opioid pain medications. This project will make use of the policy and drug consumption databases that we have developed under previous grants. In evaluating pain medication consumption statistics, we will rank and map states, dividing them into quartiles to illustrate the variation between states. Trend graphs will also be created to show changes in individual states over time.

The methodology for ranking states will be developed with review and input from consultant advisors, including Dr. Kathleen Foley, Dr. Russell Portenoy, Dr. Richard Payne, Mr. Jack Schwartz, J.D., Dr. Susan Tolle, Dr. Betty Ferrell, Ms. Myra Christopher, and Dr. June Dahl. We will also consult with communications/policy experts, including Vicki Weisfeld, Ben

Milder, Matt Bromley and Carolyn Collins. The consultant/advisors will review and comment on our work, and help us maximize the impact of this information.

(2) Prepare Annual Review of New State Pain Policies. Another key part of a national profile is to capture the dynamic nature of policy development. We propose to do this by producing an Annual Review of state pain policies that summarizes and comments on new or modified policies over the next year. This would include for example, any new medical or pharmacy board regulations and guidelines on prescribing controlled substances for pain. The Annual Reviews would contain (1) a graph depicting the cumulative trend of pain policies, and (2) a state-by-state listing, citation, summary and commentary for each new policy in the previous year. The commentary would address the positive and negative trends. We would also include, as an appendix, state maps of the medical use of opioid analgesics and the status of pain management policies, as well as the state rankings and quartile categorizations (Part 1, Item 1). Wide dissemination of this product will serve to keep the matter of state pain policy visible, and will provide yet another resource as well as a point of access to policy resources. As such, the Annual Review should be a valuable resource for policy makers, state regulatory agencies, and national and state organizations and individuals interested in pain relief, palliative and end-of-life care.

(3) Update State Pain Policies Database. Essential to the aforementioned work is the maintenance and update of the PPSG pain policy database. This will be accomplished by continuing our subscription to LEXIS. We will also periodically contact all state medical, pharmacy, and nursing boards to obtain policies that would not ordinarily be available from

LEXIS, such as some administrative codes, guidelines, and policy statements. We will broaden our policy data collection to include statements about the use of controlled substances for pain management made by other organizations such as national, state associations, and state pain commissions. We will also contact key informants who monitor the development of state pain policies to supplement data collection. This capability is essential to ensure that there is a reliable source of policy data that is available to be evaluated for the preceding projects, but also for posting on the PPSG website to provide public access to pain policy.

Part 2. Communications and Technical Assistance

Outline of Projects

- (1) Upgrade and publicize PPSG website
- (2) Increase awareness and use of PPSG products among key audiences
- (3) Technical assistance

Description of Projects

(1) Upgrade and Publicize PPSG website. The PPSG website is the heart of the communications program. With rates exceeding 100 users per day, and consistent positive

feedback as well as awards, it has become a valuable resource for information, education, and policy research. In this project, we will make further improvements to the site including materials produced under this grant and resources mentioned in preceding sections. We will update and expand links to other pain-related websites, while maintaining clarity, simplicity, efficiency and reliability. We will develop a strategy to further publicize the website among key groups, taking advantage of existing vehicles such as newsletters, websites and list serves.

(2) Increase Awareness and Use of PPSG Products Among Key Audiences. Past resources produced by the PPSG have been disseminated to key audiences via email and selected hard copy distribution, using audience lists that we have developed. We will continue and improve this approach in this project by maximizing use of our resources by organizations that are in a position to develop and implement policy affecting pain management. This will include publishing information in relevant newsletters and journals read by key enforcement and regulatory audiences, as well as participating in national conferences such as the Federation of State Medical Boards, the National Association of Boards of Pharmacy, the National Conference of State Legislators, state prosecutors, district attorneys, and medical examiners. In addition, we will maintain communication with organizations that are directly involved in the movement, such as Last Acts, Community-State Partnerships, Cancer Pain Initiatives, American Cancer Society to alert them to the release of upcoming publications and products.

We will maintain liaison with communications colleagues in the national network of mutual interests; we will update our protocols for disseminating resources, adding new individuals and groups and sharing our lists with others. Special promotional attention would be given to selected products, for example the Report Card.

(3) Technical Assistance. As the work of the PPSG becomes better known through our efforts and those who tell us that they mention our work frequently in talks around the country, we receive requests for information and technical assistance on an almost daily basis. Very key groups periodically request our review and comment on draft policies and typically incorporate our comments into the final policy. Previously, such requests have come from the American Medical Association, the American Cancer Society, the American Bar Association, the National Foundation for the Treatment of Pain, the American Pain Foundation, the National Hospice Organization, the National Conference of State Legislatures, the American Pharmaceutical Association, and the Federation of State Medical Boards. The feedback we have received on our responses has been positive. We also have provided expert testimony for educational purposes to legislative and regulatory committees.

As the level of interest in pain relief and abuse of pain medication increases, these requests appear to be increasing, probably because more and more organizations are deciding they need to become involved. In this project, we will continue to budget staff time to respond to requests for information and assistance. For example, we will be able to disseminate the report on state consumption of opioids in relation to the national average (Part 1, Item 1). These data are available to the PPSG but local groups have difficulty obtaining them. State groups have used the information effectively as one indicator to assess progress and issues in the use of opioid analgesics for pain relief.

YEAR 1							
		April '02	June '02	August '02	Oct '02	Dec '02	Feb '03 April '03
Part 1: Elements of a national profile	(1) Prepare <i>Report Card</i> on state pain policies and maps						
	(2) Prepare <i>Annual Review of New State Pain Policy</i>						
	(3) Update state pain policies database						
Part 2: Communications and technical assistance	(1) Upgrade and publicize PPSG website						
	(2) Increase awareness and use of PPSG products among key audiences						
	(3) Technical assistance						

THE
ROBERT WOOD
JOHNSON
FOUNDATION

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July 28, 2003

David E. Joranson, M.S.S.W.
Director
Pain and Policy Studies Group
University of Wisconsin-Madison
406 Science Drive, Suite 202
Madison, WI 53711-1068

Reference: I.D. #043412 - Approval of Budget Revision/Approval of Budget Extension

Dear Mr. Joranson:

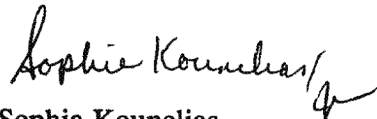
This is in reference to your Robert Wood Johnson Foundation grant in support of the Targeted End-of-Life Projects Initiative.

We have reviewed your extension request for the period July 1, 2003 to August 31, 2003, and approved it. Your final financial and narrative reports will be due by September 30, 2003.

After reviewing your budget revision request, we are approving your budget for the period May 1, 2002 to August 31, 2003. Enclosed is a revised financial reporting form reflecting your approved budget of \$200,450. This form should be used when reporting expenditures for this period.

If I can assist you further, please contact me at 609-627-5844.

Sincerely,



Sophia Kounelias
Financial Analyst

/JPW
Enclosure

cc: Robert C. Andresen
Rosemary Gibson ✓

Office of the Vice President and Treasurer

FINANCIAL REPORT**The Robert Wood Johnson Foundation**

P.O.Box 2316

Princeton, NJ 08543-2316

Phone: (609) 452-8701 Fax: (609) 627-6416

Page: 1

FA: SXX PA: JMS PO: RG

Grantee: *University of Wisconsin-Madison Medical School*

Project Director: David E. Joranson (608-263-7662)

Grant Number: 043412 for [EOL]

Fiscal Officer : Robert C. Andresen (608-262-2896)

Budget Period: May-01-2002 to Jun-30-2003

Grant Period: May-01-2002 to Jun-30-2003

Budget for Year : 1

Revised: Jul-23-2003

EXPENDITURES

Item	Approved Budget Amount	Period 1 05/02-10/02	Period 2 11/02-06/03	Period 3	Period 4	Period 5	Period 6	Total	Variance	Net
PERSONNEL										
Project Director	34,640									
Co-Director	16,274									
Sr. Policy Analyst	18,140									
Policy Analyst	9,733									
Communication Coord.	11,608									
Res. Program Mgr.	9,104									
Program Assistant	5,590									
Office Assistant	1,042									
Fringe Benefits	34,846									
Personnel Subtotal	140,977									
OTHER DIRECT COSTS										
Supplies	2,412									
Duplicating/Printing	12,505									
Postage/Shipping	4,967									
Teleconference	1,089									
Computer System Support	10,000									
Software	1,671									
Travel	7,278									
Other Direct Subtotal	39,922									
CONSULTANT/CONTRACTUAL	3,000									
Cons/Contrct Subtotal	3,000									
INDIRECT COSTS	16,551									

FINANCIAL REPORT**The Robert Wood Johnson Foundation**

P.O.Box 2316

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Page: 2

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Budget for Year : 1

Revised: Jul-23-2003

EXPENDITURES

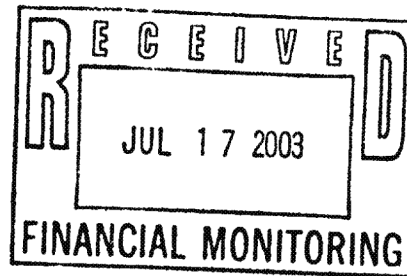
Item	Approved	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6	Total	Variance
	Budget Amount	05/02-10/02	11/02-06/03						
Grand Total	200,450								

PAIN & POLICY STUDIES GROUP



WHO Collaborating Center
for Policy and Communications
in Cancer Care

July 9, 2003



Sophia Kounelias, Financial Analyst
Robert Wood Johnson Foundation
Route 1 and College Road East
Post Office Box 2316
Princeton, NJ 08543-2316

Reference: RWJF # 043412, Pain Relief and Public Policy: Profile of a Nation
UW # 133-EU26

Dear Ms. Kounelias:

I am writing to request a two month no-cost extension from June 30, 2003 to August 31, 2003 for the above referenced grant. The revised budget and budget narrative are enclosed. We have completed writing *Achieving Balance in State Pain Policy: A Progress Report Card* and the companion policy analysis, *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (2d ed)*. The graphic design process for the Report Card took a little longer to complete than we expected, but we are very pleased with the product (example enclosed). The Evaluation Guide is too long to print economically and will be duplicated on CD. (Both reports will also be available on our website.) I am requesting the extension until August 31 to allow enough time to get the Report Card printed, the Evaluation Guide CDs duplicated, and a special order for postage processed through the UW. The complete packet will be mailed during September, which is also National Pain Awareness Month. I hope that this request meets with the approval of the Foundation.

Thank you for your assistance.

Sincerely,

A handwritten signature in cursive script, reading 'David E. Joranson'.
David E. Joranson
Senior Scientist and Director

Enclosures

Cc: Rosemary Gibson
Research & Sponsored Programs
Medical School
Comprehensive Cancer Center

Pain Relief & Public Policy: Profile of a Nation

Robert Wood Johnson Foundation - Grant #043412

Principal Investigator: David Joranson

133-EU26 A-53-3415-4

May 1, 2002 - June 30, 2003

	Approved Amount	Revision Request	Proposed Budget	Estimated Expenses Incurred (to date)
I-Personnel				
Project Dir-Joranson	\$34,485	\$155	\$34,640	\$34,640
Co-Dir-Gilson	\$16,490	(\$216)	\$16,274	\$16,274
Sr Policy Analyst-Ryan	\$18,198	(\$58)	\$18,140	\$18,140
Policy Analyst-Maurer	\$13,142	(\$3,409)	\$9,733	\$9,733
Communication Coord-Jorenby	\$11,340	\$268	\$11,608	\$11,608
Res Program Mgr-Kline/Williams	\$9,000	\$104	\$9,104	\$9,104
Program Asst-Gorman	\$5,720	(\$130)	\$5,590	\$5,590
Office Assistant	\$2,088	(\$1,046)	\$1,042	\$1,042
Subtotal Personnel	\$110,463	(\$4,332)	\$106,131	\$106,131
Fringe Benefits	\$40,016	(\$5,170)	\$34,846	\$34,846
Total Personnel	\$150,479	(\$9,502)	\$140,977	\$140,977
II-Other Direct Costs				
Supplies	\$2,820	(\$408)	\$2,412	\$1,762
Duplicating/Printing	\$3,000	\$9,505	\$12,505	\$627
Postage/Shipping	\$1,000	\$3,967	\$4,967	\$154
Teleconference	\$0	\$1,089	\$1,089	\$0
Computer System Support	\$10,000	\$0	\$10,000	\$10,000
Software	\$3,620	(\$1,949)	\$1,671	\$1,671
Travel	\$7,980	(\$702)	\$7,278	\$7,278
Total Other Direct Costs	\$28,420	\$11,502	\$39,922	\$21,492
III-Consultant/Contractual	\$5,000	(\$2,000)	\$3,000	\$3,000
Subtotal I-III	\$183,899	\$0	\$183,899	\$165,469
Indirect Costs (9%)	\$16,551	\$0	\$16,551	\$14,892
Total All Categories	\$200,450	\$0	\$200,450	\$180,361.00

jms 7/23/03

7/15/2003

2:11 PM

fundacct133-EU26rev

MDL_RWJF_0000009

BUDGET NARRATIVE – Revised Items

The budget revisions described below were made to maximize the dissemination and impact of the grant products, *Achieving Balance in State Pain Policy. A Progress Report Card* and the companion policy analysis, *Achieving Balance in Federal and State Pain Policy A Guide to Evaluation (2d ed)*. In addition to making the two reports available on our website, we propose to print 2,000 copies of the Report Card and duplicate 2,000 Evaluation Guide (500 pages) CDs. We also propose to purchase enough postage to mail 1,250 copies, with the remaining 750 copies to be distributed at meetings/conferences attended by staff.

PERSONNEL

Personnel Total (\$140,977): Reduced by \$9,502. Major changes are listed below.

Amount	Item	Explanation
(\$3,409)	Policy Analyst – Martha Maurer	Reduced time to begin work towards Ph.D.
(\$1,046)	Office Assistant	Person left for another job, was not necessary to replace
(\$5,170)	Fringe Benefits	Corresponding reduction of fringes for total of all salary adjustments
(9,502)	Personnel Total	Total reduction of all personnel line items

OTHER DIRECT COSTS

Supplies (\$2,412): Reduced by \$408. Remaining expenses include 750 double pocket folders (\$.50 each) for distributing the products at meetings/conferences, blank self-adhesive mailing labels, and a laser toner cartridge.

Duplicating/Printing (\$12,505): We have been working with a graphic designer at UW Medical Illustration and Photography to produce a professional and effective product (see enclosed examples). In addition to creating a concept look, the design work included converting the Report Card double-spaced manuscript into a professional and very readable looking report, designing a label for the Evaluation Guide CD, and designing a multi-purpose label for the mailings/folders. At the UW, the graphic designer is also responsible for obtaining competitive printing cost estimates, preparing the originals for the printer, writing the print job specifications, and acting as liaison with the printer. Specific cost estimates are given below:

\$3,100	Medical Illustration, graphic designer – estimate (\$66/hr)
\$4,700	Cost to print 2000 copies of Report Card – estimate (\$2.35 each). The 8.5x11" Report Card will have a full color gloss exterior cover, 2 color dull interior, saddle stitch binding, and cardstock insert in the center for attaching the Evaluation Guide CD.
\$450	Cost to print 2000 mailing labels – estimate (\$.225 each). The 2 color, self adhesive labels will give a custom look for both the mailings and folders.

\$3,100	Cost to duplicate 2000 Evaluation Guide CDs – estimate (\$1.50 each). The CDs will be duplicated by UW Extension Instructional Communication Systems. Besides duplication, the price includes printing a full color label on the reverse side, and a transparent vinyl sleeve with adhesive backing.
\$350	Cost to print 2000 copies letterhead for cover letter - estimate
\$500	Cost to duplicate 2000 copies of cover letter, FAQ, etc. for mailing/folders - estimate
\$305	Cost for laminated poster to present research at American Pain Society Annual Meeting, March 2003.
\$12,505	Total Duplicating/Printing

Postage/Shipping (\$4,967): The combined weight for mailing the Report Card, Evaluation Guide CD, cover letter, FAQ, and any other inserts is between 14-16 ounces, which the US Postal Service classifies as flat rate priority mail. The flat rate priority mail cardboard envelope is free, which saves us the cost of envelopes and provides extra protection for the CD, which will be attached to a card stock insert in the middle of the Report Card.

\$154	Postage costs to date.
\$4,813	Postage for 1,250 flat rate priority mailers @ \$3.85 each.
\$4,967	Total Postage

Teleconferences (\$1,089): Part of the communication plan to publicize the Report Card is the use of web teleconferences with key advocates/disseminators/partners before the general release of the Report Card in September. We propose using web teleconferences to inform and prepare these people/organizations about the content and major points. We would use the WisLine Web service of the UW Extension Instructional Communications System. WisLine Web combines audio conference calls with interactive web based materials (participants point to a pre-assigned URL to view materials). The cost for the toll free dial in number is \$ 28/minute. Depending on the number of participants and the number of web conferences, the cost/participant is given below

Cost/Participant	# of Minutes	Cost/minute
\$16.80	60 minutes	\$ 28
\$25.20	90 minutes	\$.28
\$33.60	120 minutes	\$ 28

Software (\$1,671): Reduced by \$1,949 to reflect actual expenditures. Two months into the project, we became aware that the UW-Madison Library System subscribed to the Lexis-Nexis service, which meant we were able to cancel our subscription. Other software costs included annual licenses for SPSS, Acrobat, and Macromedia Dreamweaver.

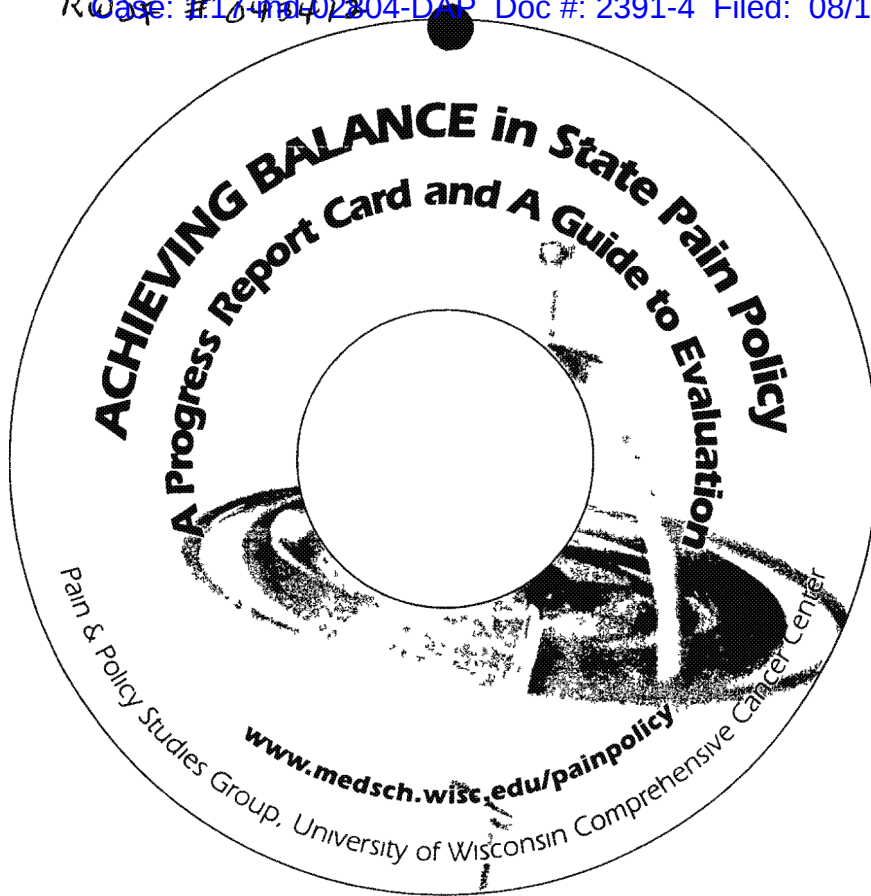
Travel (\$7,278): Reduced by \$702 to reflect actual expenditures

RWJF # 043412, UW 133-EU26
David Joranson, Principal Investigator

Page 3

CONSULTANT/CONTRACTUAL

Consultants (\$3,000): Reduced by \$2,000 to reflect actual expenditures. The amount of consultant time needed was less than originally estimated.



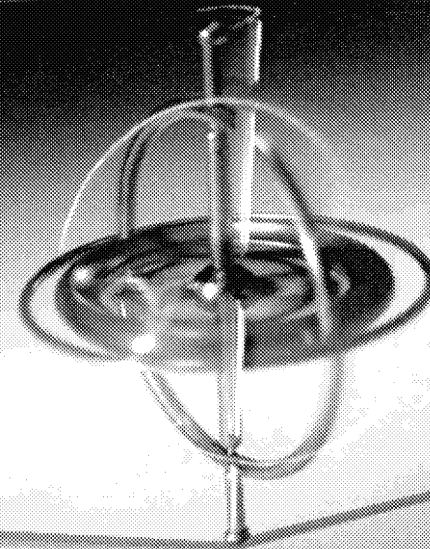
<p>Pain & Policy Studies Group University of Wisconsin Comprehensive Cancer Center 406 Science Drive, Suite 202 Madison, WI 53711-1068</p>	
<p>ACHIEVING BALANCE in State Pain Policy A Progress Report Card and A Guide to Evaluation www.medsch.wisc.edu/painpolicy</p>	

RWJF # 043412

NOT FOR DISTRIBUTION

ACHIEVING BALANCE

in State Pain Policy
A Progress Report Card



Pain & Policy Studies Group
University of Wisconsin
Comprehensive Cancer Center
www.medsch.wisc.edu/painpolicy
September 2003

Supported by:
The Robert Wood Johnson Foundation

State policies aimed at preventing drug abuse and regulating professional practice can both enhance and interfere with pain management. A three year evaluation by the University of Wisconsin Pain & Policy Studies Group shows improvement in state policies governing the medical use of opioid medications. This *Progress Report Card* grades states' policies from A to F. Along with a companion policy analysis (entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Second edition)*) it can be used by state agencies and pain relief advocates to develop plans to further improve state pain policies.

The information used to create this *Progress Report Card* is based on a systematic evaluation of the best information available to the PPSG. We hope that our conclusions and recommendations will stimulate individuals, organizations, and state agencies to engage one another to evaluate or re-evaluate their policies regarding pain management and take the necessary steps to improve and implement them. In this way, one important aspect of the pain problem can be addressed.

David E. Joranson, MSSW, Director, Senior Scientist

Aaron M. Gilson, PhD, Assistant Director

Karen M. Ryan, MA, Senior Policy Analyst

Martha A. Maurer, BS, Policy Analyst

Jody P. Jorenby, BA, Policy Analyst

Janet F. Kline, MLS, Administrative Program Specialist

The Pain & Policy Studies Group

The mission of the Pain & Policy Studies Group is to achieve more balanced international, national, and state policies so that patients' access to pain medications is not compromised by efforts to prevent diversion and drug abuse.

Recent contributions of the PPSG to improving pain management include the following publications available at www.medsch.wisc.edu/painpolicy/biblio.htm

- ◆ Workshops for members of state medical boards and an evaluation that showed improvements in their knowledge and attitudes about pain management and public policy
- ◆ Evaluation of state medical board guidelines showing that state policies improved when boards used a model policy
- ◆ Evaluation of federal and state policy often used to guide state policy evaluation and development
- ◆ Evaluation of federal and state policies on the use of controlled substances for treatment of pain in persons with a history of substance abuse
- ◆ Description of a dialog between the pain and regulatory communities about prescription monitoring programs
- ◆ Description of a state medical board's efforts to communicate new pain policies to physicians
- ◆ Analysis of a decade of change in state pain policies
- ◆ Update of trends in medical use and abuse of opioid pain medications

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EXECUTIVE SUMMARY

People are often surprised that painful conditions go unrelieved in the U.S. The consequent suffering is tragic; it is also ironic in light of existing knowledge about pain and its management. Pain, sometimes severe and debilitating, is associated with a variety of chronic diseases and conditions including cancer, sickle cell disease, and HIV/AIDS. When pain is relieved, there is improved quality of health and life. Unfortunately, inadequate management of pain occurs all too often.

Most if not all pain can be relieved if knowledgeable healthcare professionals use effective treatments, including opioid analgesics, when appropriate. There are many effective treatments for pain; opioid analgesics play an important role, especially when pain is moderate to severe. Unrelieved pain is usually due to barriers that interfere with the use of existing knowledge about pain and its treatment in everyday medical practice and patient care. There is a special set of policy-related barriers that interfere with the medical use of opioid analgesics. The focus of this report is on state policies that govern the medical use of opioid analgesics.

State policies govern the medical use of controlled substances to prevent their misuse, abuse, and diversion. When opioid analgesics are needed for patient care, these policies come into play and can interfere in medical practice. Efforts to improve state policies have resulted in positive changes, as well as unintended restrictions. This report grades each state on the extent that their policies contain language that potentially enhances or impedes pain management.

Based on policies in effect as of March 2003, 35% of states earned a grade of C, while 39% scored above a C and a quarter fell below a C. No state received an A or B. Regional grade patterns were observed for central Midwest and western states. When compared to grades based on policies from three years earlier, 14 states evidenced positive policy change. A substantial amount of the change that occurred between 2000 and 2003 resulted from three primary sources: (1) state healthcare regulatory boards adopting policies encouraging pain management, palliative care, or end of life care; (2) the repealing of single- or multiple-copy prescription programs; and (3) the rescinding of restrictive or ambiguous policy language.

Considerable positive development in state policy affecting pain management has taken place during the last decade. Although consistency in pain policy among the states is improving, it remains an elusive goal. This report represents one important part of that change. There is a continuing momentum for positive policy change that results from increasing recognition of the need to remove regulatory barriers and encourage appropriate treatment of pain. This is a balance that can be achieved if policymakers and advocates work together, use the central principle as a guide, and take advantage of the policy resources that are available. Continued cooperation between healthcare professionals and regulatory agencies will be essential to further progress. This *Progress Report Card*, used in conjunction with *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (Second edition), provides an evaluative framework for developing balanced controlled substances and medical practice policy relating to pain management in a rational and systematic way.

ACKNOWLEDGMENTS, CITATION, NOTES TO READER



Acknowledgments

The thoughtful comments of reviewers are appreciated, including June L. Dahl, PhD; William Marcus, JD; Rachel Reeder, MA; Carol Schadelbauer, BA; and Jack Schwartz, JD.

Citation

This report may be quoted or reproduced in whole or in part for educational purposes and may be cited as:

Pain & Policy Studies Group. *Achieving Balance in State Pain Policy: A Progress Report Card*. University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin. September 2003.

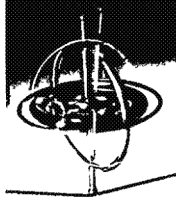
Notes to the Reader

This document is one product of the ongoing research program of the Pain & Policy Studies Group. Our purpose for making these data available is to promote education and policy change. However, their use for research purposes is limited to those who are affiliated with the Pain & Policy Studies Group or by permission.

The results presented herein pertain to policies adopted through March 2003. Individuals interested in more current policy information or in using these results to implement change can contact our office at the address below.

This publication is available on CD-ROM and on our website at www.medsch.wisc.edu/painpolicy. Requests, comments, and suggestions can be directed to:

Pain & Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
406 Science Drive, Suite 202
Madison, WI 53711
Tel: 608 263 7662
Fax: 608 263 0259
Email: ppsg@med.wisc.edu



INTRODUCTION

Unrelieved pain continues to burden Americans

It is well documented that unrelieved pain continues to be a serious public health problem for the general population in the United States.^{1,2} This issue is particularly salient for children,^{3,4} the elderly,^{5,6} minorities,^{7,8} patients with active addiction or a history of substance abuse,^{9,10} developmental disabilities,¹¹ as well as for those with serious diseases such as cancer,¹² HIV/AIDS,^{13,14} or sickle cell disease.¹⁵ Clinical experience has demonstrated that adequate pain management leads to enhanced functioning and increased quality of life, while uncontrolled pain contributes to disability and despair.

Pain can be relieved

There are many safe and effective drug and non drug ways to manage pain, which vary according to the individual needs of the patient. However, there is a general medical and regulatory consensus that opioid analgesics are necessary to maintain public health;¹⁶ they often are the mainstay of treatment, particularly if pain is severe.^{17,18} Their use for the relief of a variety of chronic non-cancer pain conditions is also clinically beneficial, although more studies are needed to guide selection of patients and use of opioids.^{19,20}

The Gap

Although medical science has learned a great deal about pain management in the last 20 years, not all of this knowledge has been incorporated into practice. Consequently, a gap exists between what is known about the medical management of pain and the actual practices of caregivers and healthcare institutions. Incomplete or inaccurate knowledge and varying attitudes about pain and the use of opioid medications can inhibit pain management.

Influence of drug abuse control policy

Opioid medications have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated pursuant to federal and state controlled substances policies, as well as under state laws and regulations that govern professional practice.²¹ Such policies are intended only to prevent drug abuse and substandard practice related to prescribing, but in some cases go well beyond the usual framework that governs controlled substances and professional practice policy and can negatively affect legitimate medical practices and create undue burdens on caregivers and patients.

Some state policies do not conform to, or conflict with, current standards of professional practice by:

- ◆ limiting the amounts that can be prescribed and dispensed
- ◆ requiring special government-issued prescription forms
- ◆ restricting access to patients who have a history of substance abuse or with addictive disease, even if they also have pain

¹ The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain-relieving properties because of their effects on the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone, and fentanyl. Opioids are often improperly referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation, while sedation can be a side effect of opioids if it is not the mechanism that produces pain relief.

INTRODUCTION



- ◆ using outdated language that confuses pain patients with people who have addictive disease
- ◆ considering opioids to be a treatment of last resort, and
- ◆ suggesting that therapeutic use of opioids may hasten death

In addition to the presence of potentially restrictive language, language that can enhance pain management is frequently absent from state policies. For example, some states do not recognize that controlled substances are necessary for the public health or that pain management is an integral part of the practice of medicine, which are policies that have been recommended by governmental authorities in controlled substances and medical practice policy.^{22,23}

The need to evaluate policy

International and national authorities, including the World Health Organization (WHO), the International Narcotics Control Board (INCB), the Institute of Medicine (IOM), the American Cancer Society (ACS), and the National Institutes of Health (NIH), have called attention to the inadequate treatment of pain and have concluded that it is due in part to drug abuse control policies that impede medical use of opioids.²⁴ These authorities have recommended evaluation and improvement of pain policies. For example, following a review of the reasons for inadequate cancer pain relief, the INCB asked all governments in the world to:

*examine the extent to which their health care systems and laws and regulations permit the use of opiates for medical purposes; identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications. (p. 17)*²⁵

The WHO has stated that better pain management could be achieved throughout the world if governments used evaluation guidelines to identify and overcome regulatory barriers to the availability and appropriate medical use of opioid analgesics.²⁶

In the US, the IOM Committee on Opportunities in Drug Abuse Research called for:

*additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain [and] for patients with addictive disorders. (p. 259)*²⁷

The IOM Committee on Care at the End of Life recommended:

revision of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies [and] reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering. (p. 198-267)

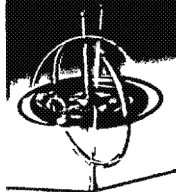
The ACS recently stated that:

*additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured. (p. 3)*²⁸

An NIH expert panel concluded that:

*Regulatory barriers need to be revised to maximize convenience, benefit, and compliance. (p. 15)*²⁹

¹ The Agency for Healthcare Policy and Research is not included as an authoritative source because its clinical practice guidelines on acute pain (1992) and neonatal pain (1994) have been withdrawn.



THE PROGRESS REPORT CARD

This *Progress Report Card*, approved for funding by the Robert Wood Johnson Foundation in May 2002, was developed in response to the need to evaluate state policies that affect pain management.⁶ It is a tool that can be used by government and non government organizations to achieve more positive and consistent state policy on the use of controlled substances for pain management (acute, cancer, and non cancer pain), palliative care, and end of life care, while not disturbing the underlying policy that opioid analgesics may only be provided for legitimate medical purposes by licensed healthcare practitioners in the course of their professional practice. The policy terms used in this report are defined in Table 1.

Table 1: Policy Terms

Policy research terms

"Pain policy" is federal or state policy that relates to pain management, in particular the use of opioid analgesics. Pain specific policies directly address pain and its management. Pain related policies indirectly affect pain management.

"Provision" is policy language that was identified as satisfying evaluation criteria.

"Positive provision" is a provision that has the potential to enhance pain management.

"Negative provision" is a provision that has the potential to impede pain management.

Policy types

"Law" is a broad term that refers to rules of conduct with binding legal force adopted by a legislative body and includes federal and state statutes and regulations. There are a number of laws relating to pain and its treatment.

"Regulation" is an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations have binding legal force and are intended to implement the administrative policies of a statutorily created agency. Regulations govern professional conduct including the treatment of pain with controlled substances, and establish what conduct is or is not acceptable for those regulated by the agency, such as physicians, pharmacists, and nurses. Regulations may not exceed an agency's statutory authority.

"Guideline" is a policy officially adopted by a government agency to express its attitude about a particular matter. While guidelines do not have binding legal force, they clarify standards of practice for those regulated by an agency. A number of state medical, pharmacy and nursing boards have issued guidelines regarding the medical use of opioids that define the conduct the board considers to be within professional practice.

Each state has been assigned a grade based on findings from two separate evaluations of federal and state pain policies in 2000 and 2003, published by the University of Wisconsin Pain & Policy Studies Group (PPSG), which are the first and second editions of *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*.^{44,45} To determine the extent of progress in the last three years, states' grades from 2003 are compared to their grades from 2000.

The *Progress Report Card* is the result of a systematic policy analysis, rather than a statement of a position about a state's pain policies. The use of a single index to compare states is useful and can draw the attention of state policy makers and healthcare professionals to the

⁶ Federal policy was not included in this report card because such policy does not regulate professional practice. Evaluation of federal policies is available in the *Evaluation Guide 2003* at www.medsch.wisc.edu/painpolicy/guide2003/index.html.

THE PROGRESS REPORT CARD



need to evaluate and improve the regulatory policy environment for pain management.⁴ We recognize that a grade oversimplifies a state's policy environment. Therefore, we are making available detailed information about the statutes, regulations, and guidelines evaluated in each state in the companion *Evaluation Guide 2003*. In addition, the complete text of each state's pain specific policies is available on the PPSG website at www.medsch.wisc.edu/painpolicy/matrix.

The central principle of balance

The *Progress Report Card* is based on evaluations of state pain policies that were guided by a central principle called *balance*, which is defined in Table 2. Balance should underlie all drug control policies so that they recognize that efforts to prevent abuse should not interfere in the medical use of opioid analgesics for patient care.

Table 2: The Central Principle of Balance

The central principle of balance represents a dual obligation of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs, while, at the same time, ensuring their medical availability.

Medical availability

- ◆ While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain.
- ◆ Opioid analgesics should be accessible to all patients who need them for relief of pain.
- ◆ Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes including:
 - empowering medical practitioners to provide opioids in the course of professional practice
 - allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and
 - ensuring that a sufficient supply of opioids is available to meet medical demand.

Drug control

- ◆ When misused, opioids pose a threat to society.
- ◆ A system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care.

(Adapted from Pain & Policy Studies Group, *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*, Second Edition, Madison, WI: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, 2003).

Appendix A presents the international and national legal and medical authorities from whose published findings concerning public policy the PPSG has derived the central principle of balance.

The evaluation criteria

The PPSG developed 17 criteria based on the principle of balance. They are divided into two categories and are used to identify positive and negative provisions in all state statutes, regulations, and guidelines (see Table 3 for a list of the individual criteria).⁶ The state grades are a measure of the quality of state pain policy in relation to the principle of balance, and are based on the frequency of provisions that meet the evaluation criteria: the higher the grade, the more balanced are a state's policies regarding opioid availability and pain management.

⁴ The adequacy of controls to prevent diversion and abuse of controlled substances is also a valid topic for the evaluation of policy. The purpose of this document is to evaluate policies affecting drug availability, medical practice, and pain management, rather than drug abuse prevention and control.

⁶ The District of Columbia is treated as a state.

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Table 3: Criteria Used to Evaluate State Pain Policies

Positive provisions: Criteria that identify policy language with the potential to enhance pain management

- 1 Controlled substances are recognized as necessary for the public health
- 2 Pain management is recognized as part of general medical practice
- 3 Medical use of opioids is recognized as legitimate professional practice
- 4 Pain management is encouraged
- 5 Practitioners' concerns about regulatory scrutiny are addressed
- 6 Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing
- 7 Physical dependence or analgesic tolerance are not confused with addiction
- 8 Other provisions that may enhance pain management

Negative provisions: Criteria that identify policy language with the potential to impede pain management

- 9 Opioids are considered a first resort
- 10 Medical use of opioids is implied to be outside legitimate professional practice
- 11 The belief that opioids hasten death is perpetuated
- 12 Physical dependence or analgesic tolerance are confused with addiction
- 13 Medical decisions are restricted
 - 13.1 Restrictions based on patient characteristics
 - 13.2 Mandated consultation
 - 13.3 Restrictions regarding quantity prescribed or dispensed
- 14 Length of prescription validity is restricted
- 15 Practitioners are subject to additional prescription requirements
- 16 Other provisions that may impede pain management
- 17 Provisions that are ambiguous

This report does not review all types of policies states can adopt to improve patient access to adequate pain management. Some states have initiated legislative and regulatory activity that has the potential to impact pain management, which falls outside of this evaluation methodology. For example, Rhode Island adopted a Pain Assessment Act in 2002 mandating healthcare professionals and organizations to conduct periodic assessments of patients' pain levels. New Jersey also introduced 5th Vital Sign legislation in 2000 requiring healthcare facilities to routinely monitor patients for pain.

This report expands on Last Acts' *Means to a Better End: A Report on Dying in America Today* by making use of current policy data to grade state pain policies. In addition, our grading methodology is different. The Last Acts report concluded that state policymakers should revise policies governing the prescribing of pain medications and work to ensure that healthcare providers are not afraid to prescribe analgesics when needed.

Readers are referred to the *Evaluation Guide 2003*, a companion to this report, for a detailed discussion of the imperative to evaluate policy, the principle of balance, the evaluation criteria, the method used to evaluate state policies, and the text of the policy provisions that were identified in each state.

¹ Last Acts is a national campaign to improve end of life care by a coalition of professional and consumer organizations. It believes in palliative care, managing pain, and making life better for individuals and families facing death.

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Two capsules are provided to elucidate the relevance of selected evaluation criteria.

**Capsule 1: Fear of Regulatory Scrutiny
Evaluation Criterion #5**

Patients

"With everything that is out there with these medications, aren't you and your license in danger from prescribing this kind of medicine?" (Statements from patients in a large university chronic pain program.)

Physicians

"Some physicians report that concern about being investigated by regulatory and licensing agencies when prescribing opioid medications for patients, including those with cancer pain and chronic non-cancer pain, leads them to prescribe lower doses or quantities of pain medication and to authorize fewer refills."^{46,47}

Regulators

Some members of state medical boards that license and investigate physicians believe that prescribing of opioids to patients with chronic non-cancer pain should be discouraged or investigated.³⁹ Knowledge and attitudes of medical board members toward opioid prescribing appear to be improving.^{48,49}

Policies

In the last decade, approximately 30 state legislatures and medical boards have adopted policies to begin addressing physicians' concerns about being investigated for legitimate prescription of opioid pain medications.

Conclusion

Despite a growing effort by policymakers and regulators, the fear of regulatory scrutiny remains a significant impediment to pain relief and will take years of further policy development, communication, and education to overcome.

**Capsule 2: Confusion about Addiction-Related Terms
Evaluation Criteria #7 & #12**

Patients

"I was openly accused of being an addict and of falsely reporting chronic pain just to obtain prescription drugs." "Some cancer patients refuse pain treatment for fear of becoming addicted."⁵⁰

Physicians and Pharmacists

Some physicians express concern that addiction or drug abuse will develop when prescribing to patients with cancer or chronic non-cancer pain.^{46,47} Some pharmacists lack knowledge of the crucial distinction between addiction, physical dependence, and tolerance.^{53,54}

Regulators

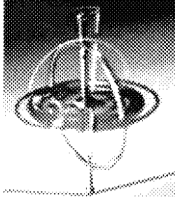
Although some state medical regulators do not understand the meaning of addiction, educational efforts have led to notable improvements in their knowledge of this concept.⁵⁰

Policies

In the last decade, approximately 24 state healthcare regulatory boards have adopted policies that correctly define addiction-related terms. Despite this progress, 16 states still have inaccurate definitions that would allow pain management to be confused with addiction.^{45,55}

Conclusion

Confusion about addiction leads to overestimation of its prevalence and is a significant impediment to pain relief. Recently adopted state policies and improved knowledge of regulators are steps in the right direction, however, a much greater systematic effort will be needed to clarify policy and educate policy makers, healthcare practitioners, and patients so that concerns about addiction are based on an accurate understanding of this disease and do not interfere with pain management.



METHOD TO ASSIGN GRADES

The PPSG used a two-step method for this analysis: (1) identify the positive and negative policy provisions in each state, and (2) assign grades.

- (1) **Identification of provisions:** The positive and negative provisions in state pain policies in 2000 had already been identified for the *Evaluation Guide 2000*.³ The PPSG updated its policy database in March 2003 using the methodology explained in the *Evaluation Guide 2003*. The criteria were then used to identify positive and negative provisions in policies current through 2003.
- (2) **Grading:** The grading method was established using the total number of positive and negative provisions identified from the *Evaluation Guide 2000*.³ Each provision was given equal weight. For 2000, the total number of positive provisions for all states ranged from 0 to 23; the average number of positive provisions per state was 5, and the standard deviation (the extent that the values deviate from the average) was 4. The range for negative provisions was 0 to 19, with an average of 4 and a standard deviation of 3; the averages and standard deviations were used to calculate the grades (see Table 4). The same grading system was then applied to the total number of positive and negative provisions identified for all states in the *Evaluation Guide 2003*.

Table 4: Grading System for Positive and Negative Provisions

Positive Provisions	Negative Provisions	Distribution
A	F	2 or more standard deviations above the average
B	D	Within 1 standard deviation above the average
C	C	Around the average
D	B	Within 1 standard deviation below the average
F	A	0 provisions

The separate positive and negative grades can be found in Appendix B and are averaged to arrive at a state's final grade; unless otherwise specified, the term "grade" refers to the final grade. Mid-point grades were calculated (B+, C+, D+), rather than rounding up or down, in an effort to reflect more precisely each state's unique combination of positive and negative provisions. For example, if a state received an A for positive provisions and a B for negative provisions, the final grade would be a B+.

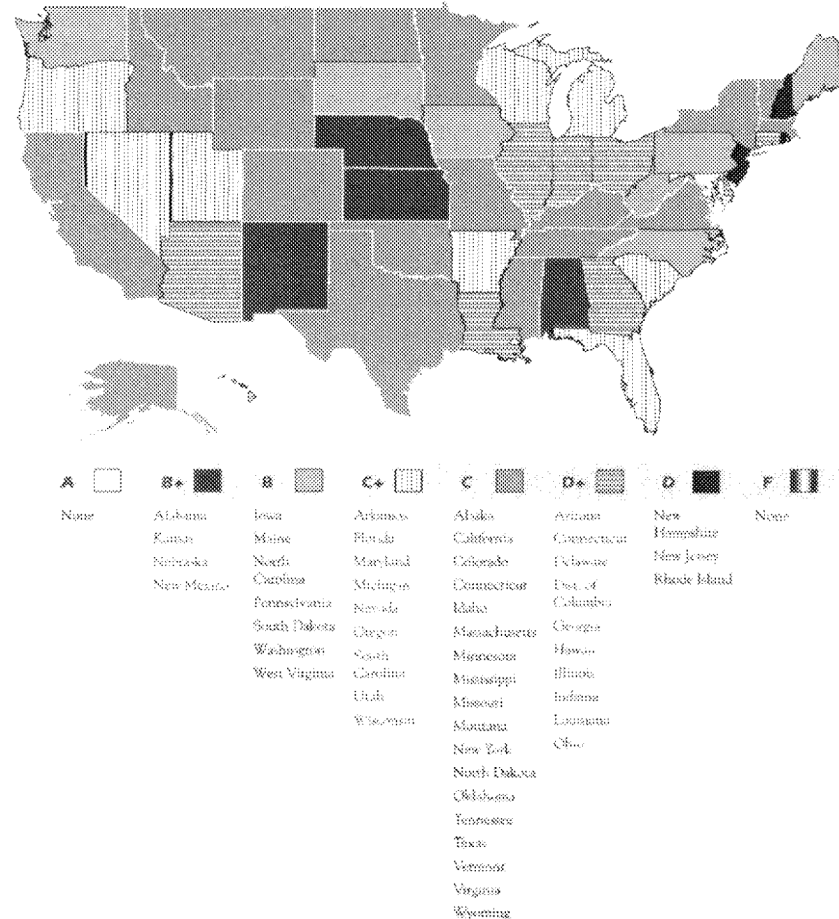
³ Grades for 2000 are based on revisions in the *Evaluation Guide 2000*.

MAKING THE GRADE: HOW DO THE STATES RATE?

Grades for 2003

Figure 1:

States' grades for 2003 are presented in Figure 1 and Table 5.



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Table 5: State Grades for 2003

STATES	2003 GRADES	STATES	2003 GRADES
AL	B+	MT	C
AK	C	NE	B+
AZ	D+	NV	C+
AR	C+	NH	D
CA	C	NJ	D
CO	C	NM	B+
CT	D+	NY	C
DE	D+	NC	B
DC	D+	ND	C
FL	C+	OH	D+
GA	D+	OK	C
HI	D	OR	C+
ID	C	PA	B
IL	D+	RI	D
IN	D+	SC	C+
IA	B	SD	B
KS	B+	TN	C
KY	C	TX	C
LA	D+	UT	C+
ME	B	VT	C
MD	C+	VA	C
MA	C	WA	B
MI	C+	WV	B
MN	C	WI	C+
MS	C	WY	C
MO	C		

Description of State Grades for 2003

- ◆ 35% of states scored around the average (thereby earning a grade of C), while 39% scored above the average and 26% fell below the average
- ◆ No state received an A or F
- ◆ A few regional patterns emerged. States in the central Midwest (Iowa, Kansas, Nebraska, and South Dakota) received Bs; the neighboring states of Illinois, Indiana, and Ohio earned grades of D+; western states (California, Colorado, Idaho, Montana, Nevada, Oregon, Utah, and Wyoming) earned grades in the C range; the three states with the largest population (California, New York, and Texas) each earned average grades of C, owing to presence of policies containing many positive provisions but also a substantial number of negative provisions.

Changes from 2000 to 2003

To evaluate changes, either positive or negative, that occurred during the three year period, 2003 grades were compared with the 2000 grades^b (see Table 6).

Table 6: State Grades, 2000 and 2003

STATES	2000 GRADES	2003 GRADES	STATES	2000 GRADES	2003 GRADES
AL	B+	B+	MT	C	C
AK	C	C	NE	B+	B+
AZ	D+	D+	NV	D	C+
AR	C+	C+	NH	D	D
CA	C	C	NJ	D	D
CO	C	C	NM	B	B+
CT	D+	D+	NY	C	C
DE	D+	D+	NC	B	B
DC	D+	D+	ND	C	C
FL	C+	C+	OH	C	D+
GA	D+	D+	OK	C	C
HI	D	D+	OR	C+	C+
ID	D	C	PA	B	B
IL	D+	D+	RI	D	D
IN	D+	D+	SC	C	C+
IA	D+	B	SD	B	B
KS	B	B+	TN	D+	C
KY	D+	C	TX	C	C
LA	D+	D+	UT	C+	C+
ME	B	B	VT	C	C
MD	C+	C+	VA	C	C
MA	D+	C	WA	B	B
MI	D+	C+	WV	C+	B
MN	C	C	WI	C	C+
MS	C	C	WY	C	C
MO	D	C			

Although no states received an A or F in either 2000 or 2003, a number of important changes occurred.

- ◆ 29% of states received above a C in 2000, increasing to 39% in 2003.
- ◆ 20 of 51 states (39%) changed their policies; the policy changes were sufficient in 15 of these states to produce a grade change – grades improved in 14 states, while one state's grade went down.

^b 2000 grades were calculated to allow comparison and measure progress, see Method to Assign Grades section.

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- ◆ Of the 14 states that improved, Iowa had the greatest improvement moving from a D+ to a B. This improvement was due to a new pharmacy board policy statement that added four positive provisions

- Criterion #3 Medical use of opioids is recognized as legitimate professional practice
- Criterion #4 Pain management is encouraged
- Criterion #5 Practitioners' concerns about regulatory scrutiny are addressed, and
- Criterion #8 Other provisions that may enhance pain management

The Iowa medical board also amended a regulation deleting two negative provisions

- Criterion #10 Medical use of opioids is implied to be outside legitimate professional practice and
- Criterion #13.2 Mandated consultation

- ◆ One state's (Ohio) grade was lowered from a C to a D+ because the state added a negative provision that perpetuates the myth that opioids hasten death [Criterion #11]. In 2000 only one provision kept Ohio from receiving a D+ therefore, the addition of a single negative provision reduced their grade in 2003

Table 7 identifies the states with positive negative and no policy change

Table 7: Grade Change in State Pain Policy Between March 2000 and March 2003

Positive Change (14 states)	Negative Change (1 state)	No Change (36 states)
Hawaii	Ohio	Alabama
Idaho		Alaska
Iowa		Arizona
Kansas		Arkansas
Kentucky		California
Massachusetts		Colorado
Michigan		Connecticut
Missouri		Delaware
Nevada		District of Columbia
New Mexico		Florida
South Carolina		Georgia
Tennessee		Illinois
West Virginia		Indiana
Wisconsin		Louisiana
		Maine
		Maryland
		Minnesota
		Mississippi
		Montana
		Nebraska
		New Hampshire
		New Jersey
		New York
		North Carolina
		North Dakota
		Oklahoma
		Oregon
		Pennsylvania
		Rhode Island
		South Dakota
		Texas
		Utah
		Vermont
		Virginia
		Washington
		Wyoming

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Reasons for the positive changes

The driving force behind the positive policy changes that occurred between 2000 and 2003 was state healthcare regulatory boards that adopted policies encouraging pain management or palliative care

- ◆ Adoption of Model Guidelines Five states (Kentucky, Missouri, Nevada, New Mexico, and Texas) adopted healthcare regulatory policies based on the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*. States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions

- Criterion #2 Pain management is recognized as part of general medical practice,
- Criterion #3 Medical use of opioids is recognized as legitimate professional practice
- Criterion #4 Pain management is encouraged,
- Criterion #5 Practitioners' concerns about regulatory scrutiny are addressed
- Criterion #6 Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7 Physical dependence or analgesic tolerance are not confused with addiction, and
- Criterion #8 Other provisions that may enhance pain management

Twenty one states have adopted the *Model Guidelines* either in whole or in part

- ◆ Adoption of Pharmacy Board policies Iowa adopted a pharmacy board policy statement relating to pain management, which added four positive provisions

- Criterion #3 Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4 Pain management is encouraged
- Criterion #5 Practitioners' concerns about regulatory scrutiny are addressed and
- Criterion #8 Other provisions that may enhance pain management

- ◆ Adoption of Joint Board Policies Three states (Kansas, Montana, and West Virginia) approved a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively by several regulatory boards such as medicine, pharmacy, and nursing, collectively, the following positive provisions were added

- Criterion #2 Pain management is recognized as part of general medical practice,
- Criterion #3 Medical use of opioids is recognized as legitimate professional practice
- Criterion #4 Pain management is encouraged
- Criterion #5 Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6 Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7 Physical dependence or analgesic tolerance are not confused with addiction, and
- Criterion #8 Other provisions that may enhance pain management

These states are Alabama, Arizona, Florida, Kansas, Kentucky, Louisiana, Maine, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia

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- ◆ Adoption of Palliative Care Policies The Missouri medical board adopted a palliative care guideline to educate physicians about the treatment of terminally ill patients adding two positive provisions

- Criterion #4 Pain management is encouraged, and
- Criterion #8 Other provisions that may enhance pain management

Positive policy change also occurred when states repealed negative provisions

- ◆ Change in Prescription Monitoring Programs Three states (Hawaii, Idaho, and Michigan) repealed their requirement for a multiple or single copy prescription form (Criterion #15) and replaced it with an Electronic Data Transfer system that does not require a special government issued prescription form. Such a change is thought to eliminate a barrier to pain management because of reluctance to obtain and use the forms and by being a less intrusive method to monitor physicians prescribing. Only three states (California, New York, and Texas) currently have a multiple or single copy prescription form requirement.
- ◆ Repeal of Restrictive Prescription Validity Periods Four states modified overly restrictive prescription validity periods (Criterion #14) from controlled substances statutes and/or regulations
 - Hawaii eliminated its 3 day period
 - Michigan eliminated a 5 day period
 - Wisconsin eliminated a 7 day period and
 - Idaho extended its validity period from 7 days to 30 days

This change eliminates the barrier of an unrealistically short validity period (i.e. the number of days within which the prescription must be dispensed following its issue), which can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements especially when travel, slow mail delivery or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and a likely return visit to the physician. Seven states have retained a validity period of less than two weeks.¹

- ◆ Repeal of Mandated Consultation Provision Three states (Iowa, Massachusetts, and Michigan) repealed provisions mandating that physicians always consult with pain specialists when using controlled substances to treat patients with pain (Criterion #13.2). Such provisions typically require a physician treating chronic non-cancer pain with opioids to obtain [an] evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system or organ of the body perceived as the source of the pain.² Although there is no question that physicians should seek consultation when needed, such a requirement may not be necessary for every case especially if the practitioner is knowledgeable about pain management. In addition, such a requirement does not appear to allow for patients who need immediate treatment. Eleven states continue to mandate consultation under certain circumstances when using opioids to treat patients with pain.³

¹ These states are California, Delaware, Illinois, Nevada, Rhode Island, Texas, and Vermont.

² These states are Arizona, California, Colorado, Idaho, Mississippi, Nevada, New York, Ohio, Oregon, Rhode Island, and Vermont.

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Despite this positive change, a few states added more restrictive provisions

- ◆ Adoption of Hastening Death Provisions Ohio and Rhode Island added language that perpetuates the misconception that the therapeutic use of opioids to relieve pain in patients at the end of life hastens death (Criterion #11). For example, Rhode Island added statutory language that provides immunity from criminal prosecution to "A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death."⁴ While the intent of the policy as a whole is to encourage pain management, it reinforces an unfounded fear about opioids⁵ that can itself contribute to inadequate treatment of pain. Such a provision is now present in 15 states.⁶
- ◆ Adoption of Provisions Mandating Opioids as Treatment of Last Resort Kentucky and Montana added provisions mandating that a physician always document that other treatment measures and drugs have been inadequate or not tolerated before beginning a regimen of controlled substances, suggesting that medical use of opioids is considered as a matter of policy a treatment of last resort (Criterion #9). Kentucky's new provision is as follows: "Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons."⁷ Currently, 10 states have policies that consider opioids to be a treatment of last resort.⁸
- ◆ Adoption of Intractable Pain Treatment Acts Tennessee adopted an Intractable Pain Treatment Act (IPTA)⁹ containing a number of restrictive or ambiguous provisions, such as implying opioids are a treatment of last resort (Criterion #9) and their use is outside legitimate professional practice (Criterion #10) and confusing "addiction" with physical dependence or tolerance (Criterion #12). As of March 2003, 11 states have adopted IPTAs containing restrictive provisions.¹⁰

¹ These states are Iowa, Indiana, Kansas, Kentucky, Maryland, Michigan, Minnesota, New Hampshire, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, and Virginia.

² These states are Arizona, Georgia, Kentucky, Louisiana, Mississippi, Montana, Ohio, Tennessee, Virginia, and West Virginia.

³ These states are California, Colorado, Minnesota, Missouri, North Dakota, Ohio, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.

CONCLUSIONS

Since 2000, legislatures and agencies in 14 states have modified their laws, regulations or guidelines sufficiently to improve their grade for balanced policy. States added a number of provisions aimed at improving pain management and removed some provisions with the potential to interfere with medical practice. Several states adopted pain-related policies that also contained additional restrictions that can impede patient access to pain care. Overall the modifications amount to excellent progress for a three-year period, but they do not take into account the extensive changes in pain policy that occurred throughout the 1990s.

Indeed, prior to 2000, a number of states adopted the *Model Guidelines* and other policies on pain management, palliative care and end-of-life care. The *Model Guidelines* and the *Evaluation Guide 2000* continue to demonstrate their value as a template for evaluating and modifying pain policy. Several states also repealed the requirement for physicians and pharmacists to use government issued prescription forms, substituting electronic prescription monitoring programs. Many of the positive policy changes that occurred between 2000 and 2003 were due to the adoption by state regulatory boards of policies encouraging pain management or palliative care. Some of the driving forces were state pain initiatives and end-of-life care coalitions that have been active in influencing state policies.^{70, 71}

Achieving balance and consistency in pain policy among the states remains an elusive goal because many negative provisions remain. Table 8 shows the number of states with statutes, regulations or guidelines that contain language meeting criteria for negative provisions.

Table 8: Number of States with Policy Language Having Potential to Impede Pain Management

Negative provisions	Number of states
9 Opioids are considered a treatment of last resort	10
10 Medical use of opioids is implied to be outside legitimate professional practice	14
11 The belief that opioids hasten death is perpetuated	15
12 Physical dependence or analgesic tolerance are confused with "addiction"	18
13 Medical decisions are restricted	5
13.1 Restrictions based on patient characteristics	11
13.2 Mandated consultation	10
13.3 Restrictions regarding quantity prescribed or dispensed	7
14 Length of prescription validity is restricted	3
15 Practitioners are subject to additional prescription requirements	15
16 Other provisions that may impede pain management	33
17 Provisions that are ambiguous	

CONCLUSIONS

It is recognized that states may enact laws or other governmental policies that are more strict than federal law. We respect the right of states to experiment and differ in their approaches to public policy, but it is necessary to ensure that all such policies are balanced and that patient care decisions requiring medical expertise are not predetermined by governmental regulation. This concept was recognized by the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care.

governments have the right to impose further restrictions if they consider it necessary to prevent diversion and misuse of opioids. However, this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes. (p. 56)⁷

Overall, the momentum for positive change in state policy continues into 2003, apparently in response to increasing national recognition of the need to improve pain management and remove policies that conflict with pain management, professional practice, and patient care. Such progress is distinguished by knowledge-based policy development in which current medical standards of medication use and pain management are understood and used to create positive public policy. This trend continues during a period of increase in both the medical use and abuse of opioid pain medications.^{64, 65} In the future, it will be important that efforts by governments and healthcare professionals to address drug abuse not interfere with legitimate medical practices and patient access to pain care. This is a balance that can be achieved if policymakers and advocates work together, use the central principle of balance as a guide, and take advantage of the policy resources that are available, our contribution to this process is policy research, model development and technical assistance to agencies and professionals.

RECOMMENDATIONS: HOW TO IMPROVE YOUR STATE'S GRADE

1. Evaluate and reform. Legislatures, professional licensing boards, and healthcare organizations are encouraged to evaluate and modify their state pain policies. In some states, ad hoc activities to improve public policy addressing pain management, end-of life care and palliative care have been established, including task forces, commissions, advisory councils and summit meetings.⁶⁶⁻⁶⁸ To achieve more balanced policy, states will need to remove restrictive or ambiguous language as well as adopt positive policies. Repeal of negative provisions is particularly important in those states that already have policies containing many positive provisions. Each state's updated policy profile is provided in *Evaluation Guide 2003* to enable identification of specific policy language in need of reform. *Evaluation Guide 2003* also contains Models for Change, a review of positive policies that can be adopted in particular the *Model Guidelines*. In addition the ACS has produced a *Toolkit* that provides concrete suggestions for achieving balanced pain policies that can benefit all patients with pain.⁶

2. Implement. Policy change with no implementation has little value. Legislatures, professional licensing boards and healthcare groups should disseminate new policies widely and repeatedly. Once a state's policies have been improved, they should be communicated to those who implement policy, including administrators, investigators, attorneys, as well as to licensees and the public. The goal is to promote broad understanding that it is the state's policy to prevent drug abuse and to encourage pain management, and that healthcare professionals who provide controlled substances responsibly have nothing to fear from regulatory agencies in the state. For example, the medical licensure boards in North Carolina and Minnesota have excelled in their efforts to communicate pain management policy to licensed physicians.⁶⁹⁻⁷⁰ The Maryland Board of Physician Quality Assurance has produced a videotape titled "A Sense of Balance: Treating Chronic Pain,"⁷¹ which is required viewing for new licensees.

3. Cooperate. Healthcare professionals should work with regulators and policymakers to evaluate and reform state pain policies.⁷² Regulatory agencies already have a track record of working with health professionals to achieve the progress described in this report, including the Drug Enforcement Administration,⁷³ state medical, pharmacy and nursing boards,⁷⁴ and prescription monitoring programs.⁷⁵ Cooperation between healthcare professionals, law enforcement, and regulatory agencies will be essential to further progress.

APPENDIX A: Authoritative Sources for the Central Principle of Balance

International sources

Single Convention on Narcotic Drugs of 1961 (United Nations, 1977)

"the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] to ensure the availability of narcotic drugs for such purposes" (p. 13)

"The Parties [national governments] shall take such legislative and administrative measures as may be necessary to limit exclusively to medical and scientific purposes the production, manufacture, distribution and possession of drugs" (p. 18-19)

World Health Organization

"Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation" (WHO, 1996 p. 58)

"those [drugs] that satisfy the health care needs of the majority of the population, they should therefore be available at all times in adequate amounts and in the appropriate dosage forms" (WHO Expert Committee on Essential Drugs, 1998 p. 2)

"These [Evaluation] Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO [and] to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability" (WHO, 2000, p. 1-2)

(1) United Nations. Single Convention on Narcotic Drugs: 1961 As Amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs: 1961. New York, NY: United Nations, 1977. (Available at http://www.incb.org/en/ind_conv.htm)

(2) World Health Organization. The Use of Essential Drugs: Eighth Report of the WHO Expert Committee (Technical Report Series 882). Geneva: Switzerland: World Health Organization, 1998.

(3) World Health Organization. Cancer Pain Relief: With a Guide to Opioid Availability. Second ed. Geneva, Switzerland: World Health Organization, 1996. (Available at <http://whqlibdoc.who.int/publications/9241544821.pdf>)

(4) World Health Organization. Achieving Balance in National Opioids Control Policy Guidelines for Assessment. Geneva, Switzerland: World Health Organization, 2000. (Available at <http://www.medicines.wisc.edu/painpolicy/publicat/00whoopi/00whoopi.htm>)

National sources

Controlled Substances Act.

"Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people" (Title 21 Controlled Substances Act §801(1))

Drug Enforcement Administration

"This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts" (Title 21 Code of Federal Regulations §1306.07(c))

"The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it." (53 Federal Register 50593, 1988)

"Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve. Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively. For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief. Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties" (Drug Enforcement Administration, Last Acts et al. 2001)

APPENDIX A: Authoritative Sources for the Central Principle of Balance (continued)

National sources (continued)

Federation of State Medical Boards of the U S (1998)

"principles of quality medical practice dictate that the people have access to appropriate and effective pain relief physicians [should] view effective pain management as a part of quality medical practice for all patients with pain All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins" (p. 1)

"Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice" (p. 2)

National Association of Attorneys General (2003)

"The National Association of Attorneys General encourages states to ensure that any such programs or strategies implemented to reduce abuse of prescription pain medications are designed with attention to their potential impact on the legitimate use of prescription drugs" (p. 2)

(1) Controlled Substances Act Pub L No 91-513 84 Stat 1242 1970

(2) Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al Promoting Pain Relief and Preventing Abuse of Pain Medications A Critical Balancing Act Washington, DC: Last Acts, 2001
(Available at <http://www.medsch.wisc.edu/painpolicy/dea01.htm>)

(3) Federation of State Medical Boards of the United States Inc Model Guidelines for the Use of Controlled Substances for the Treatment of Pain Euless, TX Federation of State Medical Boards of the United States Inc, 1998 (Available at <http://www.fsmb.org>)

(4) National Association of Attorneys General Resolution Calling for a Balanced Approach to Promoting Pain Relief and Preventing Abuse of Pain Medications Adopted at the National Association of Attorneys General Spring Meeting Washington, DC, March 17-20 2003

APPENDIX B: State Grades for Positive and Negative Provisions, 2000 and 2003

STATES	(+) GRADE 2000	(+) GRADE 2003	(-) GRADE 2000	(-) GRADE 2003
AL	B	B	A	A
AK	F	F	A	A
AZ	D	D	C	C
AR	C	C	B	B
CA	A	A	F	F
CO	B	B	D	D
CT	D	D	C	C
DE	D	D	C	C
DC	F	F	B	B
FL	B	B	C	C
GA	D	D	C	C
HI	F	F	C	B
ID	D	D	D	B
IL	F	F	B	B
IN	D	D	C	C
IA	D	B	C	B
KS	B	A	B	B
KY	D	B	C	D
LA	D	D	C	C
ME	C	C	A	A
MD	C	C	B	B
MA	D	D	C	B
MI	C	C	D	B
MN	C	C	C	C
MS	C	C	C	C
MO	C	A	F	F
MT	D	C	B	C
NE	A	A	B	B
NV	D	A	D	D
NH	F	F	C	C
NJ	D	D	D	D
NM	B	A	B	B
NY	A	A	F	F
NC	B	B	B	B
ND	C	C	C	C
OH	C	C	C	D
OK	B	B	D	D
OR	B	B	C	C
PA	B	B	B	B
RJ	C	C	F	F
SC	B	B	D	C
SD	B	B	B	B
TN	B	A	F	F
TX	A	A	F	F
UT	B	B	C	C
VT	D	D	B	B
VA	C	C	C	C
WA	B	B	B	B
WV	B	A	C	C
WI	D	D	B	A
WY	D	D	B	B

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This publication is available on CD ROM and on our website at www.medsch.wisc.edu/painpolicy. Requests, comments, and suggestions can be directed to:

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5/1/02 - 4/30/03

Robert Wood Johnson Foundation**05/01/02 to 04/30/03****Line Item Budget****I. PERSONNEL**

<u>Name</u>	<u>Position</u>		<u>Salary</u>	<u>% Effort</u>	<u>Total</u>
David E. Joranson, MSSW	Project Director	\$	98,528	35%	\$ 34,485
Aaron M. Gilson, PhD	Co-Director	\$	54,966	30%	\$ 16,490
Karen M. Ryan, MA	Sr. Policy Analyst	\$	45,494	40%	\$ 18,198
Martha A. Maurer, BS	Policy Analyst	\$	32,855	40%	\$ 13,142
Jody P. Jorenby, BA	Communication Coord	\$	28,350	40%	\$ 11,340
Carolyn M. Williams, MBA	Res. Program Mgr	\$	45,000	20%	\$ 9,000
Linda L. Gorman	Program Assistant	\$	28,600	20%	\$ 5,720
TBA	Office Assistant	\$	20,880	10%	\$ 2,088

Fringe Benefits (32.5%, *44.5%, **2%)

\$ 40,017

SUBTOTAL

\$ 150,479

II. Other Direct Costs

Supplies	\$ 2,820
Duplicating, Publications and Reprints	\$ 3,000
Postage /Shipping	\$ 1,000
Computer System Support	\$ 10,000
Software	\$ 3,620
Travel	\$ 7,980

SUBTOTAL

\$ 28,420

III. Indirect Costs (9%)\$ ~~16,101~~ 16,551**IV. Consultants**

\$ 5,000

TOTAL\$ ~~200,000~~200,450

SVIC

4/23/02

Stives, Jeanne

From: Weisfeld, Vicki
Sent: Friday, September 28, 2001 10:36 AM
To: Gibson, Rosemary
Cc: Stives, Jeanne
Subject: David Joranson proposal

Jeannie just forwarded me this for comment, and since I will be out until 10/10, I read it immediately. I know one concern earlier was the currency of DAWN data (or whatever source DJ is using to analyze diversion). The proposal says they will be able to analyze data through 2000. If there are time-trends, that sounds as good as would be possible. He wants to complete this in late 2001. I believe this component would be helpful and timely.

Second, the report card: (Bear in mind that LAX is doing a quick-and-dirty cross-state comparison and would refine its methodology based on whatever David comes up with. I've appended our criteria, drawn from the Wisconsin work and its latest publications below, FYI, and have submitted them to David for comment. He is understandably reluctant to second-guess his process proposed here by participating actively in this LAX project, however.) We in LAX certainly would use this product as part of our overall ongoing project to rank states on end-of-life issues. So, I also think this would be useful. Think of the Report Cards on child health policy that Casey has been doing for many years. They have become bibles in the child health policy field. This could be the same.

Third, diversion of pain medications website. I'm not quite clear who is the audience for this and whether these audiences think of PPSG when they want such information. There are consumer pain sites, the Am Pain Soc and other clinical groups have good sites. I think they need to analyze the "competition" a bit first before they propose this. Perhaps they could contribute some of their materials to these established entities?

Fourth, with respect to communications, of course I support that endeavor. However, if Last Acts does develop its multi-dimensional Report Card (including not just pain, but also advance directives policies, etc., etc., etc.), I would hope that David would be willing to integrate and publicize his work as a (completely credited) component of that, rather than an entirely separate entity. Dueling Report Cards would only sow confusion.